This document contains links to websites where you can find national legislation and health laws. We link to official government legal sources wherever possible. Where we link to unofficial sources this is noted and users should take this into account before relying on these materials. We recommend checking with the relevant national government if you have questions about the currency or validity of any unofficial source of law.

**Legal system**

**Civil law**

**National law database**

**Language:** Norwegian and English  
**Link:** [www.lovdata.no](http://www.lovdata.no)  
**Nature:** Legal database operated by a non-profit government organisation  
**Organisation responsible for the website:** Lovdata foundation of the ministry of justice of Norway

**Legal UHC start date**

1912

**Source:** Med Hist. 2006 January 1; 50 (1): 113-117

**The health system and policy monitor: regulation (PDF)**

As part of its Health Systems in Transition (HiT) series the European Observatory on Health Systems and Policies systematically describes the functioning of health systems in countries as well as reform and policy initiatives in progress or under development. The HiT health system reviews cover the countries of the WHO European Region as well as some additional OECD countries. This PDF includes information about the country’s regulation. To see the complete HiT report of this country go to:  
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Regulation

Norway
HIT: 2013 - Ringard Å, Sagan A, Sperre Saunes I, Lindahl AK
HSPM Members: NOKC - Norwegian Knowledge Centre for Health Services
HSPM Contributors: Ringard Å, Sagan A, Sperre Saunes I, Lindahl AK
2.8 Regulation

2.8.1 Regulation and governance of third-party payers

The key third-party payer in the Norwegian health care system is the NIS. Since 2009 the health care part of the NIS budget has been under the responsibility of the Ministry of Health. It is administrated by the Directorate of Health (i.e. HELFO) and is regulated by the 1997 National Insurance Act.

Other third-party payers are the providers of voluntary health insurance (VHI). The activity of private for-profit VHI is regulated in the general insurance legislation (the current law dates from 2005). For more information on VHI, see section 3.5. Except for the NIS and VHI providers there are no other third-party payers that are responsible for health care provision in Norway.

2.8.2 Regulation and governance of providers

Governance and regulation of specialist care

The Ministry of Health is responsible for statutory specialist care. It owns the RHAs, which are separate legal subjects, governed by independent boards. The activity of the RHAs is regulated in the 1999 Specialist Care Act, the 2001 Health Authorities and Health Trusts Act, and through the general meeting (“foretaksmøte”) between the minister and representatives of the RHAs. The RHAs own health trusts. The latter are independent legal entities with their own responsibilities as employers. They have an executive board and a general management with clear powers of authority.

The ministry provides instructions to the four RHAs through an annual “letter of instruction”. The letter is prepared individually for each RHA and is published immediately after the parliament’s decision on the national budget. The document contains tasks and specific requirements for the RHAs to follow. For example, the 2013 letter of instruction to the South-Eastern RHA contains information on the total budget placed at its disposal and some notes on specific uses of this allocation, including comments on the areas of services the ministry would like the RHA to focus more on in the coming year (Ministry of Health, 2013b).

The Directorate of Health also issues an annual circular letter to the RHAs. The letter is based upon the national budget and is intended to supplement the letter of instruction from the ministry. For example, the circular letter of 2013, which is addressed to all four RHAs, contains recommendations on issues relating to quality of care, priority setting and the implementation of e-health measures (Directorate of Health, 2013b).

Governance and regulation of primary and county level care

The governance of the municipalities and counties is in practice shared between a number of different ministries, such as the Ministry of Health, the Ministry of Labour and the Ministry of Local Government and Regional Development. The municipalities have a great deal of freedom in organizing health services. There is no direct command and control line from central authorities down to the municipalities (Johnsen, 2006). The main task of the central government is to assure the high quality of services across the municipalities through funding arrangements and legislation (e.g. the 2011 Municipal Health and Care Act).

The Directorate of Health issues an annual circular letter to the municipalities (similar to the one issued to RHAs). The circular letter of 2013 contains, for instance, recommendations on issues of quality of care, priority setting, and the implementation of different issues falling within the responsibility of the municipalities (Directorate of Health, 2013b).

Quality and patient safety

The 1999 Specialist Care Act states that every hospital must have a quality assurance commission as part
of its mandated system of internal control. Some institutions may also have quality subcommittees for each department. These commissions promote quality standards but are not responsible for ensuring that quality standards are met. The sole responsibility in this area rests with the hospital's management and staff, from the physician and nurse handling the patient, through to the chief of department and up to the hospital's director.

The 2011 Municipal Health and Care Act includes a similar requirement for primary health care providers. Each municipality must ensure that services are provided in a coordinated manner and that health care personnel have the necessary competence. Every institution that provides health and care services is also expected to work systematically to improve the quality of services and patient safety.

Systematic quality assurance is a legal requirement in Norway. Supervision of providers is consequently increasingly targeted at establishing whether systems of internal control have been implemented and whether they are functioning as required. The National Board of Health Supervision, together with its 19 County Medical Offices, has overall responsibility for the supervision and monitoring of health services in Norway. Its activities are governed by the Supervision of Health Services Act of 1984. The system audit is based on NS-ISO 10011 (1992) guidelines for auditing quality systems. The audit's focus is on: how the provider ensures an appropriate quality of service; what routines and procedures are in place; and how these are implemented and monitored in order to ensure continuous compliance and, when necessary, improvement (National Board of Health Supervision, 2002).

Both private and public hospitals are, according to the Specialist Care Act of 1999, obliged to report serious events (e.g. unexpected deaths) to the National Board of Health Supervision. From 1 July 2012, a new National Reporting and Learning System (NRLS) has been in place at the NOKC. Hospitals and other providers of specialized care are obliged to report serious adverse events as well as events that could have resulted in patient harm (i.e. near misses) caused by the delivery of health care or where injury was inflicted on one patient by another. The NRLS was set up to provide advice to the hospital reporting the incident and will also make national analyses and issue warnings and recommendations based on analyses of the reported events. Providers of primary care are currently excluded from this system.

National campaigns are another tool for improving patient safety. In January 2011, the Ministry of Health launched the Norwegian patient safety campaign "In Safe Hands". This three-year campaign aims to reduce patient harm, and involves both specialist and primary health care services. All health care trusts are expected to implement all the interventions prescribed by the campaign, within the campaign period. Primary health care providers are invited to implement all relevant interventions. The goal is to involve 25% of all municipalities by the end of 2013. The campaign will be followed by a five-year patient safety programme starting in 2014 (see section 6.2).

The 2011 Municipal Health and Care Act gave the Directorate of Health the sole responsibility to develop, disseminate and maintain national clinical guidelines. National guidelines are not legally binding but provide normative guidance on recommended courses of action. The RHAs, municipalities and management of health care institutions are responsible for facilitating the implementation of national guidelines. There are currently 400 guidelines for GPs, local health centres, nursing homes, hospitals, etc. (for very specific interventions). These are distributed to health care personnel in print and are also available online via the Electronic Health Library (see section 2.7.1).

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**Government announces plans to modify abortion laws**

By Ingrid Sperre Saunes, Anne Karin Lindahl

Norway's current abortion laws give women the right to an abortion and doctors the right to refuse to perform one. However, GPs have no right to refuse referrals. The government proposes to allow GPs who are ethically opposed to abortion to refuse referrals. GPs would have to notify all patients on their books if they are against terminations and ensure that patients considering abortion get the opportunity to see another GP within the next business day. The municipalities would be given the final say in this matter, since they contract the GPs. The plan is now open to public hearing.

2.8.3 Regulation of human resources

The Norwegian Registration Authority for Health Personnel (SAK) was established in 2001 (according to the provisions of the Health Personnel Act of 1999) and is responsible for the licensing and authorization of health care personnel (currently 29 categories). While licences impose one or more limitations with respect to duration, independent or supervised practice, an authorization represents a full and permanent approval. If the National Board of Health Supervision finds serious failure or indefensible neglect of duty it may issue a warning or, in particularly serious circumstances, withdraw the licence or approval (National Board of Health Supervision, 2002).

In general, except for GPs, there is no relicensing of health care personnel in Norway (GPs are authorized as medical doctors and licensed as GPs when they complete their specialization in general practice; all other medical specialists are authorized). GPs are required to apply for recertification every five years to retain their licence. In order to get relicensed, the GP has to document a minimum level of service in general medicine, and various other activities such as the completion of mandatory courses (e.g. in acute medicine) (see section 4.2.2).

Foreigners seeking to practise in one of the regulated professions in Norway (i.e. the 29 professions mentioned above) must have their education recognized by the Directorate of Health (for medical specialists) or SAK (for other health care professionals). In the case of professions not regulated by law, the Norwegian Agency for Quality Assurance in Education (NOKUT) assesses foreign qualifications (diplomas and grades) to compare whether they are equivalent to qualifications awarded in Norway.

2.8.4 Regulation and governance of pharmaceuticals

Regulation of pharmaceutical products

The pharmaceutical sector is one of the most regulated sectors in Norway. The NoMA is in charge of granting/withdrawing marketing authorizations and market vigilance. The regulation of pharmaceuticals is harmonized with relevant EU regulations (Norway is part of the EEA). There are thus four procedures applicants may use when applying for marketing authorization: the national procedure; mutual recognition procedure; decentralized procedure; or centralized procedure. The majority (approximately 60% in 2012) of applications are currently handled through the mutual recognition or decentralized procedures (NoMA, 2013).

All pharmaceutical companies must apply for a marketing authorization in order to sell their products on the Norwegian market. The application (national procedure) is filed to the NoMA and is normally valid for five years. The application must contain information on the quality, safety and (medical) efficacy of the product. A marketing authorization will not be issued if the potential risks associated with using a product outweigh its potential benefits. Since 2012, the total time limit for the national procedure has been harmonized with the decentralized procedure and is set to 210 calendar days (excluding “clock stop”).

The NoMA decides on the classification of pharmaceuticals. There are four prescription groups of pharmaceuticals: group A (narcotic drugs, e.g. morphine), B (addictive medicines, e.g. valium), C (other prescription-only drugs) and F (over-the-counter (OTC) drugs) (see section 5.6).

Pharmacovigilance

The NoMA is responsible for the detection and monitoring of adverse reactions of all medicinal products approved in Norway. It also contributes to the European Medicines Agency’s Pharmacovigilance Risk Assessment Committee (PRAC).

A pharmaceutical company that markets medicines in Norway (i.e. the marketing authorization holder, MAH) has the primary responsibility for the effects and safety of their medicinal products, and must ensure that it has an appropriate system of pharmacovigilance and risk management in place for those products. In order to fulfill these requirements, the MAH must ensure that all information relevant to assessing the potential risks and benefits of their products is periodically reported to the authorities through periodic
safety update reports (PSURs) and continuously through expedited reporting of individual case safety reports (ICSRs). According to the 1992 Medicinal Products Act, physicians and dentists must also report adverse drug reactions to the NoMA.

**Patent protection**

Norway is a signatory of the 1994 Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which regulates pharmaceutical patent protection between countries. Patent protection is normally granted for 20 years, which is the same as in the EU. Patents can cover: the active substance; how the active substance is produced; medical preparation (when the active substance is not new but the application is); and new medical uses (i.e. new indications) for existing drugs and formulations (e.g. tablets). A generic product cannot be put on the market if the patent has not expired (even if the market authorization period has expired).

**Advertising**

The advertising of pharmaceuticals is regulated in the 1992 Medicinal Products Act and is monitored by the NoMA. Direct advertising to patients is only allowed (including advertising on the Internet) for OTC pharmaceuticals. Promotion of OTC drugs outside pharmacies is restricted and staff handling these medicines are neither allowed to give patients any kind of recommendation nor to engage in marketing the products. Promotion of OTC drugs within the outlets is also restricted. Advertising to health care professionals cannot be combined with handing out objects, gifts, services, awards or other items of economic value. Any supply of free medicine samples to doctors is strictly regulated.

**Regulation of pharmacies and wholesalers**

The activities of pharmacies are regulated by the 2000 Pharmacy Act, which came into effect in 2001, and its associated amendments and regulations. The Act liberalized the pharmaceutical market: limitations on the ownership of pharmacies were removed (since 2001 anyone, not just pharmacists, can own a pharmacy although only pharmacists can run pharmacies), as were the limitations on establishing new pharmacies (until 2001 the NoMA regulated the number of pharmacies).

Each pharmacy must have two separate licences: one licence to own the pharmacy (the proprietor's licence) and the other to run the pharmacy (the operating licence). Only pharmacies or medicinal outlets (controlled by pharmacies) may carry out the retail sale of pharmaceutical products (although there may be exceptions, e.g. for pharmaceuticals intended for scientific use). Pharmacy chains are allowed.

Generic substitution has been allowed in Norway since 2001. Pharmacies are not allowed to substitute therapeutically (i.e. dispense a medicine with equal therapeutic benefits), but they are allowed to substitute with parallel imported medicines. The NoMA evaluates new medicines on the Norwegian market in terms of their substitutability and publishes a “substitution list”, which is updated monthly.

There are a few Internet pharmacies in Norway. Internet pharmacies are only allowed to sell OTC pharmaceuticals. Mail orders for prescription-only medicines are allowed only in the geographical district of the pharmacy, while there are no such restrictions for OTC drugs. Claw-backs are not used in Norway.

**Counterfeit drugs**

In 2012, the Ministry of Health submitted the Norwegian version of EU Directive 2011/62/EU, amending Directive 2001/83/EC on the Community code relating to medicinal products, to a national consultation process. The two EU directives aim to prevent the entry of falsified medicinal products into the market. Following the consultation in early 2013, the ministry proposed to the parliament to harmonize the 1992 Medicinal Products Act with the above EU regulations.

**Policies to improve cost-effective use of pharmaceuticals**

There are policies to improve the cost-effective use of pharmaceuticals for doctors, pharmacists and patients. In general, doctors are obliged to prescribe the cheapest equivalent product unless there are serious medical reasons for prescribing a more expensive alternative. “First-choice schemes” exist for some therapeutic equivalent medicines as an alternative to therapeutic reference pricing. The prescribing party must prescribe the first-choice product unless there are medical reasons for not doing so. First-
choice schemes promote the use of generics because off-patent active ingredients are often selected as the preferred product. International Nonproprietary Names (INN) prescribing is allowed but doctors are not obliged to prescribe by INN and currently there is not much INN prescribing in Norway. However, the NoMA is working to increase INN prescribing (the new system for electronic prescribing is expected to facilitate this).

Pharmacists are obliged to inform patients if there is a cheaper generic alternative available. If the product is reimbursed and the patient does not want to switch to the cheaper alternative, he or she will have to cover the price difference between the two alternatives out of pocket, unless the doctor puts a reservation on the prescription saying that substitution should be avoided for medical reasons. Pharmacies have financial incentives for generic substitution as higher margins can be earned on selling generic drugs (see “Pricing of prescription pharmaceuticals” below).

Rational use of medicines by patients is promoted by the state, the NoMA, patient associations and doctors. Information is available in the form of printed materials such as brochures and on the Internet. In 2009, the NoMA conducted a campaign to improve the understanding of generic substitution among prescribers and patients. Generic substitution is also indirectly promoted through reimbursement policies, such as the stepped price model (see “Pricing of prescription pharmaceuticals”).

**Pricing of prescription pharmaceuticals**

Manufacturers’ prices are not regulated and wholesalers are free to negotiate mark-ups with the manufacturers. The NoMA is responsible for setting maximum pharmacy purchase prices (PPPs). All suppliers of prescription medicines must apply for a maximum price, whether or not they are seeking reimbursement for the product. Medicines can only be sold at or below the maximum price level.

An international price referencing system has been used since July 2002 to set maximum prices for both new and existing medicines. Prices are based on the average of the three lowest PPPs in Austria, Belgium, Denmark, Finland, Germany, Ireland, the Netherlands, Sweden and the United Kingdom. If a medicine is marketed in fewer than three of the reference countries, the mean price is taken of the countries where a market price exists.

Pharmacy mark-ups for prescription products (both reimbursed and non-reimbursed) are fixed at 7% for medicines with a PPP up to NKr 200 (€27) and at 4% of the price above NKr 200. There is also a flat rate add-on of NKr 22 per pack (€3), plus value added tax (VAT) (25%). An additional flat rate add-on of NKr 10 (€1) is applied to addictive products (narcotic and psychotropic substances).

Generic prices cannot exceed the maximum market price of the original branded product. In 2005, a stepped price model was implemented in Norway, in order to reduce the public expenditure on generic drugs (i.e. drugs covered by HELFO). Under this scheme, a maximum reimbursement price is set for both branded and generic pharmaceuticals included in the scheme. The maximum reimbursement price level is automatically reduced in stages (steps) following patent expiry. The size of the price cuts depends on annual sales prior to the establishment of generic competition and time since competition was established. There are no regulations of pharmacy mark-ups within the step-price system. Pharmacies therefore have a financial incentive to carry out generic substitution and to dispense the cheaper product. Since 1995, there has been no price control on OTC medicines.

**Public reimbursement of pharmaceuticals**

There are four reimbursement categories for pharmaceuticals (see Table2.3). Schedule 2 is in essence a “positive list” system (the so-called “blue list”), based on a list of medicines that can be reimbursed for specified diagnoses (see also section 3.3.1).

Reimbursement decisions for non-hospitals medicines are made by the NoMA. When applying for reimbursement, pharmaceutical companies need to follow the Norwegian guidelines for pharmacoeconomic evaluations. The guidelines ask for: an explanation of the choice of comparison; the time frame of the analysis; data collection methods; analysis methods; and costs. Cost-effectiveness analysis is well established in Norway and the use of quality-adjusted life-years (QALYs) as a parameter is increasing. No maximum willingness to pay per QALY has been defined. For products associated with a substantial cost to the public budget, decisions on reimbursement are taken by the Ministry of Health. The
HELFO decides on reimbursement for individual patients for pharmaceuticals without general reimbursement or indications not covered by general reimbursement (see Schedules 3a and 3b in Table 2.3).

Pharmaceutical and therapeutic committees in hospitals have traditionally decided on the inclusion of medicines in the hospital pharmaceutical formulary for internal use, but this may change with the system for the introduction of new technologies from 2013 (see section 6.1.6). There are no countrywide medicines lists for inpatient care.

Table 23:

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


New report on pharmaceutical policy published – more focus on research

In May 2015 the Minister of Health and Care Services presented a new report on pharmaceutical policy to the Storting (parliament) titled “Proper use – improved health”. The previous report was presented a decade ago, also by a centre–right coalition. The report sets out three main policy objectives, building on the previous report: ensure good quality in all pharmaceutical treatment; improve regulation in order to contain costs and ensure equal and efficient access to effective pharmaceuticals. The new policy element added in the 2015 report is the introduction of a plan for development of pharmaceutical registries (scheduled for 2016), which is a response to the National Strategy for Research and Innovation (see policy update published on 11 November 2014) that calls for supporting innovation and research. Other measures included in the report are aimed at supporting clinical studies and providing improved information to patients. The Parliament has also lifted the ban on the advertising of OTC medicines on television and on the Internet from January 2016.

https://www.regjeringen.no/no/tema/helse-og-omsorg/legemidler/innsikt/legemiddelmeldingen-richt-bruk-bedre-helse/id2413036/

https://www.regjeringen.no/no/aktuelt/tillater-tv-reklame-for-reseptfrie-legemidler/id2458625/

2.8.5 Regulation of medical devices and aids

The market for medical devices and aids, including manufacturing and technical market access, is regulated by the Directorate of Health, according to the 1995 Medical Devices Act. The EU Medical Device

2.8.6 Regulation of capital investment

Investment decisions are taken by the RHAs (specialist care) and the municipalities (primary care), and coordination of capital investments is low both across different levels of care and geographically (see section 4.1.1).