HEALTHCARE FINANCING AND REIMBURSEMENT: A GLOBAL REVIEW OF MAJOR TOPICS AND TRENDS

Authors:
Nicole Kien and Claudia de Geus, LS&H Lawyers & Mediators
kien@lshlawyers.nl

LAWS AND REGULATIONS ON HEALTHCARE FINANCING AND REIMBURSEMENT

1. Please provide a bird's eyes view on the healthcare economy, indicating, in general terms, the role of the government (public healthcare) and private actors (private healthcare).

The Dutch healthcare system can be described as a regulated market model. The government sets the framework and rules and private actors are responsible for providing and delivering healthcare services within that framework. The government regulates the healthcare system, ensuring universal coverage and access to quality healthcare services.

Municipalities have been given far-reaching tasks related to the social domain since decentralisation in 2015. These include youth care and care for the long-term sick and elderly. Municipalities also have an important role in public healthcare, dealing with health promotion and protection measures for both the general population and specific groups.

The national government is responsible for setting out the law governing the provision of healthcare. Municipalities are responsible for local interpretation and implementation. There are no nationally established funding rules. Each municipality sets its own rules around the funding of prevention, care, support and youth assistance like conditions to access these services and the method of payment. The expenses are part of the municipal budget. Regardless of legal responsibilities/opportunities, municipalities can choose to promote prevention by paying for initiatives from their own financial resources, based on their social commitment.

Basic health insurance is mandatory and regulated in the Netherlands. All healthcare insurers are private companies. Most healthcare providers are also private entities, however they are still subject to government regulations concerning pricing, quality standards, and patient care. There are both public and private hospitals.

2. Please provide a high-level overview of the legal framework regarding healthcare financing and reimbursement.

Financing and reimbursement are mainly covered by the Health Insurance Act (*Zvw* or *Zorgverzekeringswet*). The Zvw regulates that everyone who lives or pays income tax in the Netherlands is legally required to have basic insurance. This basic insurance covers standard care, such as care given by general practitioners, hospitals and pharmacies. In addition, anyone can take out (voluntary) supplementary insurance for costs not covered by the basic package. The Health Insurance Decree regulates the medical care which must be covered by basic health insurance packages, including indicated and care-related prevention meaning that

the coverage includes curative care (treatment of diseases) as well as certain forms of prevention such as preventative care provided to people diagnosed with an increased risk of a certain condition, and care that is provided to prevent the worsening of an existing disease or complication.

The Long-Term Care Act (*Wlz*) entitles people to care who are permanently dependent on 24-hour close care or permanent supervision. Wlz care is financed by a national insurance scheme to which every taxpayer contributes. This money goes to care offices (which form part of the major health insurance companies) from central government coffers.

The Health Care Market Regulation Act (*Wmg*) provides the ground rules and associated supervision for the regulated market model. Among other things, the law promotes that where necessary, the government can regulate tariffs and performance ('prestaties').

Health insurers and healthcare providers go through an annual (or multiannual) healthcare purchasing process. Every year healthcare insurers set their healthcare purchasing policies, and care providers can determine whether they wish to enter into a contract with a healthcare insurer partly on that basis. In the purchasing policy, healthcare insurers describe their criteria for purchasing care (eg, hospital care, mental health care and general practitioner care).

Healthcare insurers and providers from different sectors have agreed among themselves on rules of conduct, or good contracting practices, for the healthcare procurement process. These are set out in the NZa (see the response to question 3) and contain agreements on care procurement, transparency and timing.

3. What are the key regulators and supervisory bodies regarding healthcare financing and reimbursement?

The Dutch Healthcare Authority (*NZa*) plays an import role in overseeing the reimbursement process. It ensures that the market operates fairly, promotes competition, and regulates healthcare prices. It ensures that the reimbursement rates for healthcare services are appropriate and that insurers comply with the regulations concerning the basic insurance package.

As an independent regulator, the Consumer & Market Authority (ACM) monitors and promotes competition in the Netherlands, including within the healthcare market.

The Zorginstituut Nederland (ZIN, or 'Health Care Institute') plays an indispensable role in the implementation of financing and keeping healthcare in the Netherlands on track and affordable. It manages the Health Insurance Fund (*Zvf*) for the Health Insurance Act (*Zvw*) and the Long-Term Care Fund (*Flz*) for the Long-Term Care Act (*Wlz*). Healthcare insurers, care offices and care institutions receive payments from these funds to arrange care. Another important task of the Health Care Institute is appropriate package management ('passend pakketbeheer'). The Health Care Institute advises the Minister of Health, Welfare and Sport on the quality, access and affordability of the basic package. In addition, the Health Care Institute clarifies the basic package. If it is unclear in practice whether certain care belongs to the basic package, the Health Care Institute can prepare a statement about this in a 'position paper'.

Courts can also play a role in price and tariff matters too. For example, when healthcare insurers make decisions about reimbursement, courts can assess the legality of coverage denials.

4. Has there been a change with healthcare financing and reimbursement as a consequence of the Covid-19 pandemic?

During the Covid-19 pandemic there were some temporary changes in healthcare financing and reimbursement in the Netherlands. Some of the changes are likely to have long-lasting effects. Due to the Covid-19 outbreak, out of necessity much care was delivered remotely using e-health. Its use has been made easier, the Dutch government extended funding and conditions for its operation and this continues.

5. Who has access to the healthcare system as a patient on the one side and as a medical service provider/supplier of medical goods on the other side? What are the conditions of admission?

Limits of general patient access to medicine (age, nationality, residence, etc.)

Healthcare insurance for basic medical services is mandatory for every resident and ensures equal access to the healthcare system in principle. Every healthcare insurer has generally to accept every resident as an insured at the same level of premium. There is no differentiation in premiums for age, residence, etc. except that minors (under 18) do not pay premiums. Insurers retain full contractual freedom for voluntary additional insurance, meaning they may refuse to accept a person as an insured. This additional insurance is financed by extra premiums paid by the respective insureds and covers services and goods not covered by mandatory health insurance.

Access of healthcare providers to public funding/ reimbursement by (mandatory) health insurers

A licence requirement applies to healthcare providers who provide (or arrange for the provision of) care as defined in the Health Insurance Act or Long-Term Care Act.

Pharmaceuticals first must be authorised by the CBG (*College ter Beoordeling van Geneesmiddelen*) or the European Union's EMA (European Medicines Agency), the authority responsible for granting marketing authorisations.

Dutch legislation distinguishes between intramural (medications used in a hospital) and extramural drugs (drugs delivered and administered outside of a hospital) for the reimbursement. Extramural drugs are only reimbursed from the basic package when they are included in the so-called medicines reimbursement schedule (GVS). The amount of reimbursement depends on the list on which they are placed in the schedule. The Minister of VWS decides whether or not a drug will be included in the GVS, mostly following ZIN advice.

In principle, intramural medicines are automatically part of the insured basic package, provided that the drug meets the legal criterion of the 'state of the art science and practice'

(SW&P) and a patient reasonably needs it. Intramural drugs automatically become part of the basic insurance package in a process also known as 'open inflow'. However, open inflow is limited in practice at both central and decentralised levels, as an assessment must be undertaken before awarding a reimbursement.

The assessments are carried out differently. Centrally, drugs with a high price or a high macro cost impact are placed by the Ministry of VWS in 'the lock for expensive medicines' (in short: lock, '*sluis*') and a ZIN assessment is required. For decentralised assessments a ZN committee (the *Commissie Beoordeling Add On Geneesmiddelen at Zorgverzekeraars Nederland*) assesses the medicine before reimbursement is granted. This is possibly followed by a negotiation on price with the Clean Team coordinated by ZN.

For medical devices, it is primarily up to the health insurance company to assess whether a new device qualifies for reimbursement from the basic health insurance package. This is also called whether a device 'falls under the function-based entitlement'. It is also up to the health insurer to assess whether a new device meets the legal criterion of SW&P; in other words, whether the device has been proven effective.

Special cases (treatment of residents abroad, emergency treatment of non-residents etc.)

For (emergency) treatment of residents abroad, the basic health insurance provides worldwide coverage. The cost of care abroad is reimbursed up to the rate normal in the Netherlands. For non-emergency care, which is booked in advance for residents abroad, additional permission from the health insurer is usually required in advance. Treatment abroad is reimbursed only if the treatment is also reimbursed at home. EU rules on medical treatment abroad cover medical and dental care, medicines and hospitalisation.

Non-residents can be treated for emergencies in the Netherlands. They will either require a European Insurance Card (EHIC), the condition of which also apply for health coverage as Netherlands residents, or travel insurance which covers health costs.

HEALTH INSURANCE FINANCING AND COVERAGE

6. How are health insurance carriers financed? How are premiums determined?

The insured person pays a monthly premium to the healthcare insurer for their basic insurance. An insured up to the age of 18 do not pay a premium and are insured for healthcare costs free of charge. Most care in the basic package is subject to excess. The government determines the amount of the compulsory excess ('*eigen risico*'). This applies per year and per person aged 18 and over. A personal contribution ('*eigen bijdrage*') may also apply. The government determines which care this personal contribution applies to and how much it costs.

The nominal premium consists of two parts: the calculation premium and the storage premium. The calculation premium is set by the Minister of Health, Welfare and Sport and is the same for each health insurer. The storage premium is set by health insurers themselves and therefore varies from one insurer to another. This premium is determined by the following criteria:

- the insurer's operating costs – the costs an insurer incurs to implement the Health Insurance Act (*Zvw*);
- reserves (solvency);
- other surcharges – including costs incurred when insured default on their premiums and/or excesses;
- deficits or surpluses due to risk equalisation – all income-dependent contributions enter the health insurance fund, insurers then receive a payment from the fund according to a certain calculation model, the payment depends on the characteristics of the health insurer's insured population; and
- (possibly) a surcharge for profit – most health insurers do not aim to make a profit for the implementation of basic insurance.

This applies only to the premium for basic insurance. The premium for optional supplementary insurance is entirely set by the health insurer.

Apart from the premiums, about 50 per cent of all care in the basic package is paid for through the Health Insurance Fund, which is financed by income-dependent (employer) contributions and taxes. These are collectively raised by employers, employees, the self-employed, and benefit agencies (withholding agents). The government also pays a state contribution for those up to 18 years of age.

The option of going to court is always available. If it is believed a premium has been set too high, or that a health insurer has not followed the rules in setting the premium, insured persons can go to court or file a complaint at the *Nationale Ombudsman*. In more extreme cases the fairness or legality of the premium-related regulations may be challenged, which could lead to a case being reviewed by an administrative court and ultimately even the Dutch Council of State (*Afdeling bestuursrechtspraak van de Raad van State*).

7. How is coverage of medical services by health insurance carriers regulated? Are there differences in coverage for in person medical appointments and telemedicine appointments?

All mandatory health insurance providers must cover the same basic set of services, pharmaceuticals, and medical devices, all defined by law. See the response to question 5 for the explanation of who decides on coverage. With the understanding that the basic coverage is provided, healthcare insurers are allowed to have preferences and diverge.

Special cases (telemedicine, orphan drugs, off-label use, etc.)

The insurance coverage for in person visits and tele-medical appointments is the same.

In general, medicines are eligible for reimbursement regardless of the indications for which they are prescribed. The Minister of VWS however did link the right to reimbursement for a number of medicines to indications.

For orphan drugs, ZIN reviews whether they can be reimbursed from the basic package.

HOSPITAL SECTOR

8. How are services provided by hospitals in the stationary (inpatient) and ambulatory (outpatient) settings financed and reimbursed?

See response to question 5 for the reimbursement of intramural/extramural medicines.

For hospital treatment as an inpatient the Diagnosis Treatment Combination (DBC) system is applicable. The rate of a DBC is based on an average of the care provided and the associated average cost of care. In addition to DBCs, there are also Other Healthcare Products (OZP). These are listed as a separate activity on the hospital bill. The Dutch Healthcare Authority (NZa) determines the content and description of healthcare products (DBC products). The NZa does this on behalf of the Ministry of Health, Welfare and Sport (VWS). The level of the average fee for a healthcare product is determined jointly by health insurers and hospitals.

The NZa sets a maximum price for some care products. For some care, hospitals and health insurers are not allowed to negotiate. These are subject to a fixed contribution. For example, this is the case with trauma care and donor acceptance teams. Most inpatient services are covered by the basic insurance package.

For services in outpatient settings, hospitals are also reimbursed for outpatient services through the DBC system. Additionally, certain hospitals or healthcare providers may also receive performance-based payments or capitation (fixed payments per patient) for specific outpatient services. The basic insurance package covers most outpatient hospital services.

The GP (general practitioner) plays an important role in outpatient care. They are the first point of contact for patients, and many outpatient services are initiated and referred through them. GP costs are covered by the mandatory basic health insurance.

9. How are the prices of such services determined? How is economic efficiency controlled?

See response to question 8.

HEALTHCARE PROVIDERS IN PRIVATE PRACTICE

10. How are services provided by physicians, therapists, laboratories and other service providers financed and reimbursed?

See response to question 8. In the Netherlands, these healthcare services are primarily financed through a mandatory health insurance system. Citizens must have basic health insurance, covering most physician, therapist, and laboratory services. Providers are reimbursed via fixed tariffs negotiated between insurance companies and healthcare providers, with additional funding for specialised care.

11. How are the prices of such services determined? How is economic efficiency controlled?

See responses to questions 8, 9, and 10.

PHARMACEUTICALS AND MEDICAL DEVICES

12. How are pharmaceuticals and medical devices financed and reimbursed?

Coverage by public/mandatory health insurance and/or funding by the government / Coverage by private/optional health insurance and/or self-payment by patients

See response to question 5.

Pharmaceuticals and medical devices which fall within the basic health insurance package, are partly financed through the mandatory health insurance. Residents aged 18 years and over are required to pay monthly premiums to the private health insurers. Apart from the premiums, the care in the basic package is paid for through the Health Insurance Fund, which is financed by income-dependent (employer) contributions and taxes. These are collectively raised by employees, employers, the self-employed, and benefit agencies (withholding agents). The government also pays a state contribution for the under 18s.

As also explained, most care in the basic package is subject to compulsory deductible excess. The government determines the amount of the deductible excess ('*eigen risico*'). This applies per year and per person aged 18 and over. This means that up to the amount of the '*eigen risico*' (in 2025: €385), patients need to pay for the pharmaceuticals/medical devices themselves first when the care falls within the basic insurance package. A personal contribution ('*eigen bijdrage*') may also apply. The government determines for which care the personal contribution applies and its cost.

Pharmaceuticals and medical devices which are not in the basic health insurance package are paid by patients themselves or can be (partly) covered by optional health insurance.

Derogatory cases such as orphan drugs or early access products

If the orphan drug has a market authorisation and is part of the basic health insurance package it will be reimbursed by the mandatory health insurance (in the same was as explained above). However, this may have been preceded by price negotiations and ultimately an agreement between the Minister of Health and the manufacturer about a price decrease. There is currently a pilot project in the Netherlands to accelerate access to treatments for non-oncological rare diseases that have projected sales too low for them to be included in the lock for high-price drugs. It combines patient-level outcomes-based reimbursement with population-level coverage with evidence development.

When treatment is not yet eligible for regular reimbursement, an early access programme can provide assistance. This allows drugs to become available to patients after the market authorisation test, while waiting for a final reimbursement decision. Manufacturers are sometimes willing to make their drugs available to patients free of charge during the lock-in period, therefore bearing the costs themselves.

13. How are the prices of pharmaceuticals and medical devices determined? How is economic efficiency controlled?

For pharmaceuticals to be reimbursed, the Dutch Health Institute (*Zorginstituut Nederland*) assesses whether care can be reimbursed from the basic health insurance package. Cost effectiveness is one of the criteria in this assessment.

Medicines are also subject to maximum prices in the Netherlands. These are listed in the Medicines Pricing Act. The maximum price is determined by the average of the prices for similar medicines in four reference countries. As of 15 December 2019, these are countries are Belgium, France, Norway, and the United Kingdom.

Health insurance companies only reimburse medications patients receive from pharmacies if they are registered and included in the Drug Reimbursement System (GVS). The GVS contains about 400 different groups of medicines. The drugs within such a group or cluster are interchangeable. Each cluster in the GVS has a maximum reimbursement. If a drug's price exceeds this reimbursement limit, the patient must pay the difference.

New, expensive drugs do not simply enter the basic health insurance package. The Minister can temporarily keep new drugs out of the basic health insurance package. The drugs are then placed 'in the lock'. During that period, the Care Institute can issue an opinion, and the Minister has time to negotiate pricing with the manufacturer.

Most health insurance companies usually only reimburse the cheapest version of medications with the same active ingredient. This is called the preference or preferential policy.

For medical devices, pricing is the result of negotiations between the healthcare insurer and medical devices provider.

LITIGATION INVOLVING HEALTHCARE FINANCING AND REIMBURSEMENT

14. Please provide a high-level overview of major litigation topics and landmark cases regarding healthcare financing and reimbursement.

Cases on limits to public/mandatory health insurance funding in individual cases (eg, maximum spending per additional life year)

HR 19 DECEMBER 2014, ECLI:NL:HR:2014:3679

In exceptional cases, a health insurance company is entitled to reimbursement for care that is not part of the basic package, according to the Supreme Court in a ruling on an 11-year-old girl suffering from a very rare disease. The Court stated that the insurer should reimburse the drug because the only reason the drug is not part of the basic package for children is that insufficient research had been carried out.

HR 9 JULY 2021, ECLI:NL:HR:2021:1111

The Minister of VWS determines which drugs are part of the basic health insurance package. Health insurers may then designate which drugs are within the package they will reimburse ('preferred drugs'), but they must reimburse at least one drug of each active ingredient. A health insurer may limit the reimbursable strengths of a drug with a given active ingredient to one or a few strengths. But if a doctor prescribes a different drug, strength or dosage for medical reasons, the pharmacist must dispense it and the health insurer must reimburse it. In doing so, the health insurer may not impose any conditions or restrictions.

Cases on emergency financing of hospitals and other service providers in financial distress

There has been a lot of discussion at the national level about whether or not a hospital in financial distress should be supported by healthcare insurers or government. The status quo is that an arrangement should be made if the distance of accessible hospital care exceeds a 45-minute drive. Health insurance companies are legally required to secure access to necessary care for insured patients. Recently a large primary care organisation (Co-Med) went bankrupt even though there is a shortage of primary care providers in the Netherlands. There have been no landmark cases.

Cases on access to orphan drugs or early access products

There is no specific 'landmark' case about access to orphan drugs or early access products. However, there have been several legal proceedings about the question as to whether an orphan drug should be reimbursed through basic insurance.

RECENT DEVELOPMENTS AND TRENDS

15. What are the recent developments and trends for the next few years? Please outline any unresolved issues, proposed changes, or trends for healthcare financing and reimbursement and briefly indicate how these may foreseeably affect the medical sector in the near future.

The accessibility, quality and affordability of the Dutch healthcare system are under pressure. The current organisation of healthcare, both in terms of demand on the labour market and public finances, is not sustainable. Measures are required.

The deductible will be frozen at €385 in 2025 and 2026 and sharply reduced to €165 from 2027. And in hospital, a maximum of €50 per treatment benefit will apply. As this is a substantial reduction, a legislative period of two years is applied. People with lower incomes are to receive an increased care allowance. The healthcare premium, which will rise correspondingly as a result of the public-private relations set out in the Health Insurance Act, will be fully compensated on balance for citizens via a reduction in income tax and for companies via the employed persons' insurance contributions (AOF) premium. The substantial decrease in the deductible excess involves a net intensification of €4.3bn. It is expected that with a substantially lower deductible, more people will be referred to a medical specialist in case of complaints.

Drug availability at pharmacies is a major concern in 2025. A number of improvements are already under way. Shortages are addressed earlier more appropriately in order to look for timely solutions for patients. The government and practitioners are examining what the alternatives are and/or allowing the import of comparable medicines from abroad. The government is making the Dutch market more attractive to drug manufacturers by assessing pricing and reimbursement instruments, such as the Medicines Pricing Act (WGP) and the Medicines Reimbursement System (GVS) but also the preference policy. Also, additional supplies are manufactured stockpiled to cope with increased demand or temporary production disruption.

The creation, advancement and implementation of technological and social innovations are encouraged. The foundations are being laid for the further development and deployment of AI. Preparations are also being made for the EU's European Health Dataspace (EHDS) regulation which will come into force in 2025.

Ongoing litigation re fundamental issue(s), expected judgments

A proceeding is currently underway which addresses whether a drug manufacturer acted unlawfully and abused its economic dominance by overcharging for its drug (ECLI:NL:RBAMS:2024:4255).

A pharmaceutical company's lawsuit against the Authority Consumer and Market (ACM) is also ongoing, following fines imposed for high drug prices and thereby abuse of economic dominance (ACM/21/053339).