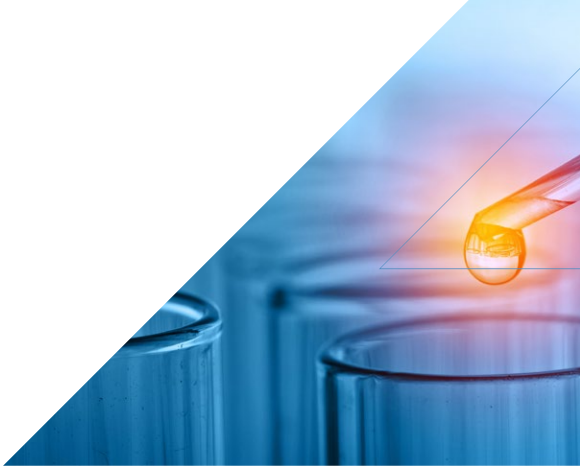
HEALTHCARE IN THE NETHERLANDS

HOUTHOFF



HEALTHCARE IN THE NETHERLANDS

A guide to key legal and regulatory issues in health and life sciences transactions 2021

1 THE IMPACT OF COVID-19 ON THE PROVISION OF HEALTHCARE AND LIFE SCIENCES

The COVID-19 pandemic has had a significant effect on the Dutch healthcare system. Even though a large proportion of the Dutch inhabitants has been vaccinated, the rise in infections has led to a prioritisation of COVID-19 related healthcare services at the expense of 'regular' healthcare. The Dutch government is considering providing 'booster' vaccines as the extensive COVID testing programme has not curbed a rise in infections. In an effort to minimise infections there has also been a significant rise in teleconsultation both by general practitioners and hospitals.

Manufacturers, purchasers and suppliers may only supply CE-marked mouth masks and gloves to healthcare providers as of 1 October 2021. Until 1 June 2022, healthcare providers may still use mouth masks and gloves without CE marking if they still have them in stock.

2 OWNERSHIP OR EQUIVALENT RESTRICTIONS IN RELATION TO THE PROVISION OF HEALTHCARE SERVICES

A healthcare provider must obtain a licence to provide healthcare services. These services are reimbursed by either healthcare insurers (basic healthcare) or the Dutch state (long-term care). The license procedure will change as of 1 January 2022. In order to improve monitoring compliance with (quality) regulations, under certain conditions both licensed healthcare providers as well as their subcontractors need to notify their activities to the appointed authorities.

Healthcare professionals must be registered in accordance with the Individual Healthcare Professions Act.

For specific forms of healthcare, a provider with a licence is not allowed to distribute profits. Sub-contractors fall outside this prohibition.

3 REIMBURSEMENT OF PUBLIC OR NATIONAL HEALTHCARE SERVICES AND AWARD OF CONTRACTS

All residents in the Netherlands must take out basic healthcare insurance. Healthcare insurers have a duty of care which means that they cannot refuse to provide basic insurance for any individual. In order to provide for affordable, high quality, timely and accessible healthcare, insurers conclude annual contracts with healthcare providers to ensure basic care for their clients. In most situations, the invoices are paid directly to the providers. Insurers receive monthly premiums and, depending on the insured population, compensation from the government. Under certain circumstances, insured individuals must pay deductibles as well as a maximised own risk. Academic hospitals receive additional

"Clients appreciate the firm for its 'sound, pragmatic and tailor-made advice.'"

(CHAMBERS EUROPE, HEALTHCARE (2021 EDITION)

contributions from the government. If insured individuals receive non-contracted care, insurers are not obliged to fully reimburse the costs.

With regard to long-term care, healthcare providers also contract separately with insurers subsidiaries, mostly on an annual basis. An independent institution decides per patient whether there is a need for long-term care. The coverage is fully paid by public money raised through taxation.

4 DRUG APPROVALS AND REIMBURSEMENT

A registration and marketing authorisation (MA) is required to stock, sell, distribute, deliver, make available within or import drugs into the Netherlands.

If the centralised procedure for obtaining an MA via the European Medicines Agency (EMA) does not apply, the Dutch Medicines Evaluation Board (MEB) is responsible for registering drugs and delivering the MA for marketing the drugs in the Netherlands.

The MEB decides whether a drug must be available by prescription only from a doctor or specialist (PO) or whether a drug is available without prescription over-the-counter (OTC). OTC drugs are divided into three categories: (i) pharmacy-only drugs (PH) with a relatively mild potential risk, (ii) Pharmacy and Drugstore only drugs (PDO) with a relatively low potential risk, and (iii) General Sales drugs (GS) with very low risk that are also available via sales channels such as supermarkets or service stations.

The Ministry of Health, Welfare and Sports (MoH) has the possibility to determine the maximum allowable prices for drugs biannually. When purchasing drugs, pharmacists may not pay more than the maximum prices.

Dutch healthcare insurers will only reimburse a registered drug if it is included in the Drug Reimbursement System. The MoH and the Healthcare Institute of the Netherlands decide together which drugs fall within the standard healthcare insurance coverage and whether they are either fully or partially reimbursable. OTC drugs are not reimbursable.

5 DEVICES CERTIFICATION AND REIMBURSEMENT

In order to place a medical device on the Dutch market, it must comply with the requirements of the Medical Device Regulation (MDR), the Dutch Medical Devices Decree and the In Vitro Diagnostic Medical Devices Decree. The Health and Youth Care inspectorate is the relevant authority.

For marketing purposes in the Netherlands, a medical device must comply with the essential requirements of Annex I of the MDR and labels and instructions must be in the Dutch language. If the medical device complies with the essential requirements and the correct procedures have been followed, the medical device must bear the CE mark confirming its conformity. Class I device manufacturers can assess the conformity of the product themselves. Medical devices Class IIa, IIb and III must be inspected by an independent and accredited organisation that is designated by the government (notified body).

Manufacturers have to be established in the European Union or must have an authorised representative in the European Union and must register with EUDAMED.

There are various laws and regulations in the Netherlands for reimbursement of medical devices. Most medical devices are reimbursed based on the Dutch Health Insurance Act. The Healthcare Insurance Regulations describes which medical devices qualify for reimbursement under basic healthcare insurance cover. Healthcare insurers assess whether a new medical device is covered by basic healthcare insurance and, therefore, if it qualifies for reimbursement. Healthcare insurers may set additional conditions for reimbursement, such as a requirement for their grant of permission prior to use. Healthcare insurers also assess whether a device has been proven to be effective.

6 REGULATION OF AI AND SOFTWARE AS A MEDICAL DEVICE

AI and big data in healthcare and the legal and ethical questions that they raise are hot topics in the Netherlands.

E-health apps are considered to be medical devices and must comply with the Medical Devices Regulation (MDR) from 26 May 2021.

The GDPR and the Dutch Processing of Personal Data in Healthcare (Additional Provisions) Act regulate the use of software and medical apps in the healthcare sector and the associated use of medical and non-medical data.

7 TELEMEDICINE AND TELECONSULTATION

In the Netherlands, the government is encouraging the healthcare sector to expand telehealth. As such, the MoH published an Assessment Framework 'Deployment of e-health by healthcare providers' in 2018, which provides standards and related assessment criteria with respect to telehealth.

In principle, teleconsultation is reimbursable by Dutch healthcare insurers, provided that certain conditions are met. Dutch law is rather restrictive in relation to online prescriptions. It is prohibited for a prescriber to prescribe drugs to any individual if the prescriber has not met the individual in person, does not know the individual or does not have access to the individual's medical history. The MoH has noted that the prohibition regarding prescriptions does not apply to healthcare professionals who are established in other EU Member States. This view is in line with the EU E-Commerce Directive and the EU Cross-Border Healthcare Directive.

However, due to the COVID-19 pandemic, the MoH has decided to allow online prescription of drugs in situations where the prescriber has not met a patient in person before, at least until 1 January 2022.

8 ANTI-KICKBACK RULES AND INCENTIVES TO DOCTORS

Dutch inducement rules prohibit the promising, offering or giving of money, valuable services or goods with the 'apparent purpose' of promoting prescribing, providing or using a drug or the sale of a medical device. Exceptions apply, for instance, for gifts of limited monetary value that can be used for professional practice. There are detailed rules for calculating fines for infringements, which take into account the size of the undertaking.

Undertakings with registered offices outside of the Netherlands can be fined if they infringe the inducement rules and the infringement has a manifest effect in the Netherlands.

Under the applicable self-regulatory framework on financial relationships between the industry and medical professionals, payments to healthcare professionals (excluding general practitioners) exceeding EUR 500 must be notified in a transparency register.

9 MERGER AND FOREIGN INVESTMENT CONTROL

Apart from certain utilities sectors, the Netherlands has a liberal policy towards foreign investment. There is no general requirement for prior approval of investments made by foreign legal entities or foreign natural persons in the healthcare sector.

A new bill on investment control, the Investment Screening Bill (*Wet Veiligheidstoets investeringen, fusies en overnames (Wet Vifo), the* **ISB)** is pending which is intended to have retroactive effect from 8 September 2020 onwards. The bill includes a filing obligation for any acquirer where the target is involved in vital processes or working with sensitive technologies in the Netherlands. The healthcare sector is not defined as a vital process in the current draft bill. However, additional vital processes can be added, but any addition must be confirmed by formal law.

If a proposed merger or acquisition involves a healthcare provider that employs 50 or more individuals that provide healthcare, a prior notification to the Dutch Healthcare Authority (NZa) is mandatory. The NZa is also the designated regulator capable of taking measures if a healthcare provider or healthcare insurer has significant market power.

Mergers in the healthcare sector are subject to lowered turnover thresholds for notification to the Dutch Competition Authority (ACM). A transaction has to be notified if: (i) the worldwide turnover of all undertakings concerned is more than EUR 55 million, and (ii) at least two of the undertakings achieve a turnover of more than EUR 10 million in the Netherlands.

10 FORTHCOMING AND ANTICIPATED CHANGES IN HEALTHCARE AND LIFE SCIENCES LAW

As of 2022 the Act on Healthcare and Care Providers (Accreditation) Act (in Dutch: *Wet toetreding zorgaanbieders or* **WTZa**) and accompanying acts (including *Aanpassingswet WTZa or* **AWTZa**) will enter into force. The WTZa will change the licensing system for healthcare institutions in order to improve supervision and awareness of the applicable quality rules and regulations. The WTZa will replace the current licensing system as laid down in the Care Institutions (Accreditation) Act (in Dutch: *Wet Toelating Zorginstellingen or* **WTZi**. The WTZi will remain in force in relation to the profit distribution ban for specific healthcare providers.

"The most important quality is knowing how to influence people and Houthoff is good at building relationships."

(LEGAL 500, HEALTHCARE & LIFE SCIENCES (2021 EDITION)

The most significant changes include in short:

- Existing healthcare providers must notify the health inspectorate (IGJ) about the care they provide within 6 months after the WTZa enters into force. The notification is a rather administrative procedure including completing a form of the IGJ.
- Some healthcare providers are also obliged to obtain a license under the WTZa. For obtaining and keeping such licence, they must fulfil certain conditions amongst others relating to the governance structure. Insofar the existing healthcare provider already applied for a licence under the WTZi, the provider will automatically receive an accreditation under the WTZa. Other healthcare providers must apply for such license. For existing and new healthcare providers there is a transition period of 2 years to comply with the licensing conditions.
- Healthcare providers must comply with the quality standards as laid down in the Healthcare Quality, Complaints and Disputes Act (in Dutch: *Wet klachten en geschillen zorg* or **Wkkgz**), public reporting and financial transparency requirements, and also requirements regarding client representation.
- Under conditions aforementioned obligations are also applicable to subcontractors that provide healthcare.

A new guidance on access to medical records by next of kin from the Royal Dutch Society for the Advancement of Medicine was approved on 26 November 2020.

In May 2020 a proposal has been published which, inter alia, amends the current Dutch GDPR implementation act (*Uitvoeringswet AVG*) with respect to the transfer of personal data from medical records to other parties than healthcare providers in case of bankruptcy, retirement or the decease of a healthcare provider. This proposal is still under consultation.

In addition, the following bills have been sent to the House of Representatives for evaluation:

- A bill on digital exchange of data in healthcare has been approved by the Council of Ministers.
- In March 2020, a bill introducing a Transparency Register for Healthcare was submitted. Every transaction between manufacturer and doctor of 50 euros or more is registered. In June 2021, the Dutch Data Privacy Authority issued advice to the House of Representatives criticizing this bill. According to the Dutch Data Privacy Authority a registration in the Transparency Register for Healthcare is a considerable intrusion on the privacy of the individual practitioner. They have doubts whether the transparency of the register is necessary and whether access to the register could not be limited to the health inspectorate (IGJ).
- Members of the House of Representatives have proposed an amendment to the Healthcare Quality, Complaints and Disputes Act to increase the involvement of healthcare employees in decisions made by healthcare institutions that affect the way in which healthcare is provided.
- A bill on the transfer of statutory duties regarding merger control and the control of significant market power from the Dutch Healthcare Authority to the Netherlands Authority for Consumers and Markets (the Dutch competition regulator). The bill will also amend the thresholds for prior mandatory notification.

In July 2021, an Order in Council was issued that aims to strengthen the possibilities to combat various forms of fraud (inter alia in the healthcare sector) by the use of the Personal Records Database (*Basisregistratie Personen*). This Order in Council has been criticized from a privacy perspective. The consultation period ended 7 September 2021.

In May 2021, a temporary bill on COVID access certificates was passed. This bill makes it possible, when taking measures to combat COVID-19, to introduce rules on a required test certificate indicating if a person was infected with the coronavirus at the time the test was taken.

In February 2021, the Dutch Data Protection Authority issued advice about a proposed Order in Council in relation to the consultation of client data via an electronic exchange system in connection with the triage or treatment of COVID-19. The Dutch Data Protection Authority raised serious objections to this proposal. No definitive Order in Council has been issued yet. As a prompt availability of medical data of COVID-19 patients in emergencies is deemed necessary, this data is currently exchanged based on a tolerance arrangement pending an appropriate legal basis.

Team

Our multi-disciplinary Healthcare Team is actively involved in the public debate on the healthcare of the future. Our specialists provide valuable input on the major challenges facing the healthcare sector, whether this be at macro-level or at the level of one or more individual providers. Our Healthcare Team offers practical solutions that help improve healthcare.

GERRIT OOSTERHUIS
ADVOCAAT | PARTNER
EU & COMPETITION
g.oosterhuis@houthoff.com

WEYER VERLOREN VAN THEMAAT
ADVOCAAT | PARTNER
EU & COMPETITION
w.verloren@houthoff.com

THOMAS DE WEERD
ADVOCAAT | PARTNER
INTELLECTUAL PROPERTY
t.de.weerd@houthoff.com

GREETJE VAN HEEZIK
ADVOCAAT | COUNSEL
EU REGULATORY
g.van.heezik@houthoff.com

FREEKE HEIJNE
ADVOCAAT | COUNSEL
HEALTH LAW
f.heijne@houthoff.com

FLEUR TUINZING-WESTERHUIS
ADVOCAAT | COUNSEL
INTELLECTUAL PROPERTY
f.tuinzing@houthoff.com

MURAT DUMAN
ADVOCAAT | SR. ASSOCIATE
EU & COMPETITION |
HEALTH LAW
m.duman@houthoff.com

JURRE REUS
ADVOCAAT | SR. ASSOCIATE
INTELLECTUAL PROPERTY
j.reus@houthoff.com

JORI DE GOFFAU
ADVOCAAT | ASSOCIATE
EU & COMPETITION
j.de.goffau@houthoff.com