The Pharma Legal Handbook

The Netherlands

Regulatory, Pricing and Reimbursement Overview · Preclinical and Clinical Trial Requirements · Marketing, Manufacturing, Packaging and Labeling Advertising · Traditional Medicines and OTC Products · Product Liability · Patents and Trademarks · Regulatory Reforms · Cannabinoid Drugs, Medicinal Cannabis and Opioid Drugs · Orphan Drugs and Rare Diseases · Localization · Biosimilars and Biologics

PHARMA BOARDROOM

The Netherlands

The Pharma Legal Handbook answers essential questions about this environment for pharmaceuticals in The Netherlands. It is a must have for any company operating in the country or looking to enter the market.

Prepared in association with HOUTHOFF, a leading law firm law firm in The Netherlands, it should answer any questions linked to Regulation, Pricing, Clinical and Preclinical Trials, Marketing, Manufacturing, Trademarks and Patents.

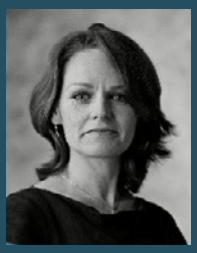
*** THIS REPORT WAS ORIGINALLY PUBLISHED IN AUGUST 2023 AND THE INFORMATION CONTAINED WITHIN IS SUBJECT TO CHANGE.**

HOUTHOFF

Houthoff is a leading independent Dutch law firm, with offices in Amsterdam, Rotterdam, Brussels, London and New York, as well as representatives in Houston, Singapore and Tokyo.

Houthoff's Life Sciences Team works for companies and organisations in the areas of biotechnology, the pharmaceutical industry, biomedical technologies, innovative foodstuffs, health claims, cosmetics, and medical devices. The team advises clients in all stages of product development up and till product launch, including R&D collaborations, protection of IP and technology, licensing and technology transfer, and all regulatory aspects of use of genetic resources and marketing of medicines and medical devices. The Life Sciences Team also advises on matters at the interface between market protection and free parallel trade within the EU internal market and under the Specific Mechanism. Houthoff's Life Sciences Team employs a multi-disciplinary approach, understands the scientific, ethical and business challenges of the sector, and offers practical and commercially applicable advice.

THE AUTHORS



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Greetje specialises in EU Regulatory & Competition law. She frequently advises companies active in the pharmaceutical and medical devices sector on the regulatory requirements relating to the authorisation, marketing, packaging, labelling, product quality and pricing of medical devices and pharmaceutical products, including medicinal cannabis.

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Fleur Tuinzing-Westerhuis specialises in Intellectual Property matters, with a focus on patents and technology. In her daily practice, Fleur represents a wide variety of domestic and international companies that are active in the biotech and life sciences sector, including start-ups, universities, leading multinationals and investors. Fleur is an experienced patent litigator and has broad experience in advising on commercial contracts, including R&D agreements, license and technology transfer agreements.

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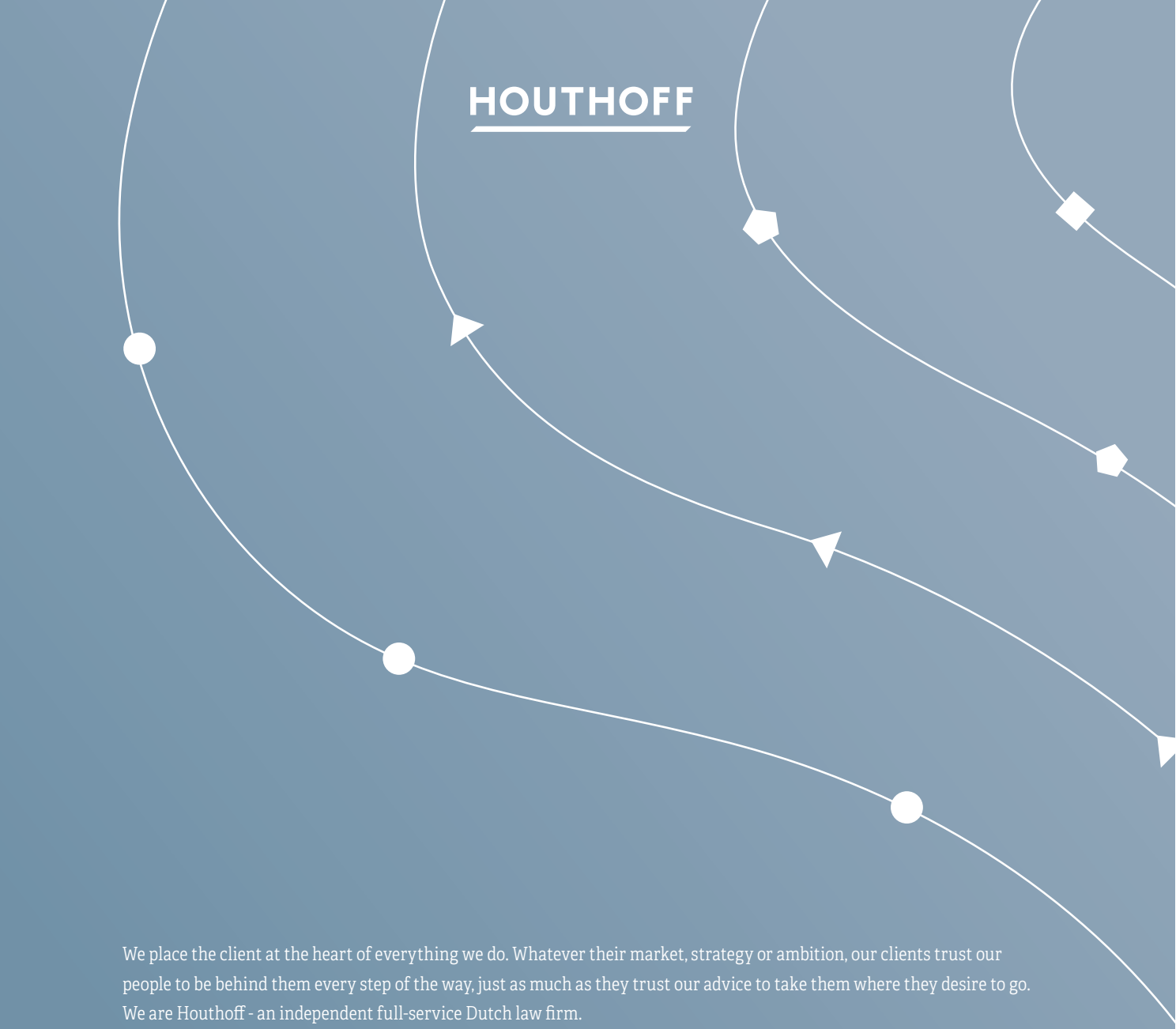
FREEKE HEIJNE

Freeke specialises in government and regulation and is an expert in healthcare regulation, including the regulatory requirements for healthcare providers and the healthcare reimbursement system. As a board room advisor she regularly deals with delicate and societal sensitive matters both in and outside court rooms. The clientele includes a variety of stakeholders including healthcare providers, insurers and private equity. She is also a member of the Dutch Association for Health Law.



We place the client at the heart of everything we do. Whatever their market, strategy or ambition, our clients trust our people to be behind them every step of the way, just as much as they trust our advice to take them where they desire to go. We are Houthoff - an independent full-service Dutch law firm.

With offices in Amsterdam, Rotterdam, Brussels, London and New York, as well as representatives in Houston, Tokyo and Shanghai, we are able to offer an extensive global service network. Leading legal directories acknowledge in depth our strengths. As the exclusive member firm in the Netherlands for Lex Mundi and TechLaw, we can provide our clients seamless access to some of the world's finest law firms. In addition to our own extensive and highly prized network of experts, we work collaboratively with our clients to ensure their international success.

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01 REGULATORY, PRICING, AND REIMBURSEMENT OVERVIEW

1. What are the regulatory authorities with jurisdiction over drugs, biologicals, and medical devices in your country?

Ministry of Health, Welfare and Sport (*Ministerie van Volksgezondheid, Welzijn en Sport*)

The policy and regulation of drugs ('medicinal products'), biologicals and medical devices falls under the jurisdiction of the Ministry of Health, Welfare and Sport. The Ministry has the primary responsibility for the Dutch healthcare system. It has delegated most of its executive and supervisory tasks to governmental bodies.

Medicines Evaluation Board (*College ter Beoordeling van Geneesmiddelen*) ("**MEB**")

The MEB is the governmental body that is responsible for the assessment of medicinal products, the registration of medicinal products, the issuing of marketing authorizations and the monitoring of adverse reactions and risks (i.e. pharmacovigilance).

Farmatec

Farmatec is part of the Central Information Unit on Healthcare Professions (*Centraal Informatiepunt Beroepen Gezondheidszorg, (CIBG)*), which is an implementing organization of the Ministry of Health, Welfare and Sport. Farmatec's responsibilities include, the granting of pharmaceutical licenses (i.e. wholesale and manufacturing permits), the registration of certain medical devices, the setting of maximum prices for medicinal products, the issuing of Certificates of Pharmaceutical Products (CPP) for the export of pharmaceutical products, and the granting of exemptions for the marketing of opioid drugs.

Health and Youth Care Inspectorate *(Inspectie Gezondheid en Jeudzorg*, (IGJ)) ("**Inspectorate**")

The Inspectorate is generally responsible for supervising compliance with the regulatory framework. The Inspectorate enforces the regulatory requirements concerning the safety of medical devices as well as medicinal products. Its tasks include the supervision of the 'Good Practices' throughout the supply chain, pharmacovigilance, the monitoring of adherence to the registration and authorization requirements, product recalls, and the requirements regarding inducement, transparency and marketing. However, responsibility for supervising compliance with the regulatory framework within the armed forces lies with the Ministry of Defense. Supervision is carried out by a military-medical inspection body. The Ministry of Transport and Water Management has primary responsibility for the requirements concerning the provision of

medicinal products on board commercial shipping vessels. The Maritime Division of the Human Environment and Transport Inspectorate (Inspectie Leefomgeving en Transport) is tasked with the supervision and enforcement of these requirements.

Other

The Foundation for the Code for Pharmaceutical Advertising (*Stichting Code Geneesmiddelenreclame (CGR)*) lays down rules of conduct for prescription drug advertising and cooperation between healthcare providers and pharmaceutical companies.

The Healthcare Transparency Register Foundation (*Stichting Transparantieregister Zorg*) is an implementing organization that ensures the disclosure of financial relationships between healthcare providers and industry in a central register, the Healthcare Transparency Register (*Transparantieregister Zorg*). The Healthcare Transparency Register includes information provided by companies, healthcare providers and healthcare institutions pursuant to the Code of Conduct for Medical Devices (*Gedragscode Medische Hulpmiddelen*) (see further **Question 2** of this Chapter) and the Code of Conduct for Pharmaceutical Advertising (*Gedragscode Geneesmiddelenreclame*) (see further **Chapter 3, Question 38**).

2. What is the regulatory framework for the authorization, pricing, and reimbursement of drugs, biologicals, and medical devices?

Drugs (medicinal products)

The Medicines Act (*Geneesmiddelenwet*) contains the requirements concerning the production and marketing of medicinal products and also provides for the implementation in Dutch law of Directive (EU) 2001/83 on medicinal products for human use. Implementing measures follow from the Medicines Act Regulation (*Regeling Geneesmiddelenwet*) and the Medicines Act Decree (*Besluit Geneesmiddelenwet*). The Medicine Prices Act (*Regeling maximumprijzen geneesmiddelen*) sets maximum allowable prices for medicinal products in the Netherlands. The rules on the reimbursement of medicinal products are tied in with the national health insurance system.

Biologicals

Biologicals are included in the Medicines Act. Therefore, biologicals are not addressed separately in the remainder of this contribution unless they are treated differently.

Medical devices

Regulation (EU) 2017/745 on medical devices ("**MDR**") and Regulation (EU) 2017/746 on in vitro diagnostic medical devices ("**IVDR**") apply directly to medical devices produced, placed on the market and offered to patients in the Netherlands (including via e-commerce). These regulations have direct effect and do not require transposition into Dutch law. The Medical Devices Implementing Regulation (*Regeling medische hulpmiddelen*) sets language requirements and designates competent authorities for the implementation of the MDR and the IVDR. Additional national requirements and requirements

relating to the application of these regulations are laid down in the Medical Devices Act (*Wet medische hulpmiddelen*). The implementing rules relating to this act concerning medical devices are laid down in the Medical Devices Decree (*Besluit medische hulpmiddelen*) and the implementing rules concerning in vitro diagnostics are laid down in the In Vitro Diagnostic Medical Devices Decree (*Besluit in-vitro diagnostica*).

Moreover, a private Code of Conduct for medical devices aims to elaborate, in addition to the applicable legislation, on a careful, transparent and responsible relationship between suppliers of medical devices and the parties involved in the decision-making about their purchase and/or application. A sizeable number of medical device suppliers adhere to this code.

Reimbursement

Most medicinal products and medicinal devices are reimbursed on the basis of either the Healthcare Insurance Act (*Zorgverzekeringswet*) or the Long-Term Care Act (*Wet langdurige zorg*) and the accompanying regulations, e.g. the Healthcare Insurance Regulation (*Regeling Zorgverzekering*) and the Long-Term Care Regulation (*Regeling langdurige zorg*) (see further **Questions 10 to 13** of this Chapter).

3. What are the steps to obtaining authorization to develop, test, and market a product?

Drugs (medicinal products)

Development and testing

Authorization for new clinical trials (drug research) must be obtained from the Member State in which the drug research takes place, via the procedure prescribed by the Clinical Trial Regulation (EU) 536/2014 ("**CTR**"). The CTR entered into force on 31 January 2022 and replaces the Clinical Trials Directive 2001/20/EC. The Netherlands had implemented this Directive in the Medical Research (Human Subjects) Act (Wet medisch-wetenschappelijk onderzoek met mensen, ''**MRA**"). With the entry into force of the CTR, Directive 2001/20/EC was repealed, as well as Article 5a of the MRA, which specifically concerned drug research. From 31 January 2022 onwards, a three-year transition period applies for drug studies approved under the Directive 2001/20/EC and the MRA to the CTR. As from 31 January 2023, the CTR applies to all new applications for drug research. Under the CTR, a single procedure for submission, assessment and conduct of drug research applies to all drug studies (national and multinational) conducted in the European Economic Area (EEA). Clinical trial applications must be submitted via the Clinical Trials Information System ("**CTIS**"), which is maintained by the European Medicines Agency ("**EMA**"). The authorization and oversight of clinical trials remains the responsibility of the Member States. The CTIS is maintained by the EMA and is the single entry point for submitting the clinical trial application in the EU. From 31 January 2025 onwards, all current drug studies that have been approved under the old framework must comply with the CTR requirements as well. The MRA requirements remain applicable to other forms of medical research that do not fall within the scope of the CTR (see further **Chapter 2**).