The Pharma Legal Handbook

Germany

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

PHARMA BOARDROOM

Germany

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

Prepared in association with HEUKING KÜHN LÜER WOJTEK, a leading german law firm practicing out of eight german offices in Berlin, Chemnitz Düsseldorf, Frankfurt, Hamburg, Cologne, Munich, Stuttgart and Offices in Brussels, Belgium; and Zurich, Switzerland. It should answer any questions linked to Regulation, Pricing, Clinical and Preclinical Trials, Marketing, Manufacturing, Trademarks and Patents.

*** THIS REPORT WAS ORIGINALLY PUBLISHED IN NOVEMBER 2019 AND THE INFORMATION CONTAINED WITHIN IS SUBJECT TO CHANGE.**

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The firm's about 400 lawyers, tax advisors and notaries provide comprehensive legal services in German and international business law, including regulatory and commercial advice in essentially all sectors of health care.

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THE AUTHORS

RUDOLF DU MESNIL DE ROCHEMONT

MARKET AUTHORIZATIONS, PRICING, TRIAL REQUIREMENTS, PACKAGING, ADVERTISING

Rudolf du Mesnil de Rochemont is a partner in the firm's Frankfurt office, advising clients in the sectors of pharmaceutical and medical device law, IP, licensing, distribution, advertising, general commercial law and international transactions. He studied and practiced in 1974 and 1975 in New York, before he became a member of Heuking Kühn Lüer Wojtek. Mr du Mesnil is Past Chairman and a Member of the Committees on Intellectual Property Law, Business Organization and M&A of the Section on Business Law of the International Bar Association, Past Section Council Member, Past President and Honorary Member of the German American Lawyers Association, Member of the International Association for the Protection of Industrial Property and other professional organizations.

Languages: German, English

KAI RUNKEL

TRADITIONAL MEDICINES, OTC, PRODUCT LIABILITY

Kai Runkel is a salaried partner in the Cologne office of Heuking Kühn Lüer Wojtek. He is a Certified Specialist Lawyer in Intellectual Property Law with a particular focus on trademark law, unfair competition issues (including advertising law) and the regulations of product manufacturing and marketing. Industry sectors of Mr. Runkel's clients include the pharmaceuticals and medical devices industries. Mr Runkel represents national and international clients in and out of court throughout Germany. He is a member of the German and International Association for the Protection of Industrial Property.

Languages: German, English

DR SABINE DETHOF

PATENTS AND TRADEMARKS

Sabine Dethof is a salaried partner in the Düsseldorf office of Heuking Kühn Lüer Wojtek. She is a Certified Specialist Lawyer in Intellectual Property Law and specialised in patent litigation. She represents international clients in patent litigation proceedings before all major courts. She is also experienced in nullity proceedings before the Federal Patent Court and the Federal Court of Justice.

Languages: German, English

PHILIPP ROMAN SCHRÖLER

PATENTS AND TRADEMARKS

Philipp Schröler is a senior associate in the firm's Düsseldorf office, specialising in intellectual property law, particularly patent litigation. Before joining Heuking Kühn Lüer Wojtek he was a lawyer in the IP department of two other major international law firms. He has extensive experience in complex international patent litigation in the field of pharmaceuticals, in particular with regard to the market launch of biosimilars. In this context, he also has particular expertise in the enforcement of patents by way of preliminary injunctions.

Languages: German, English

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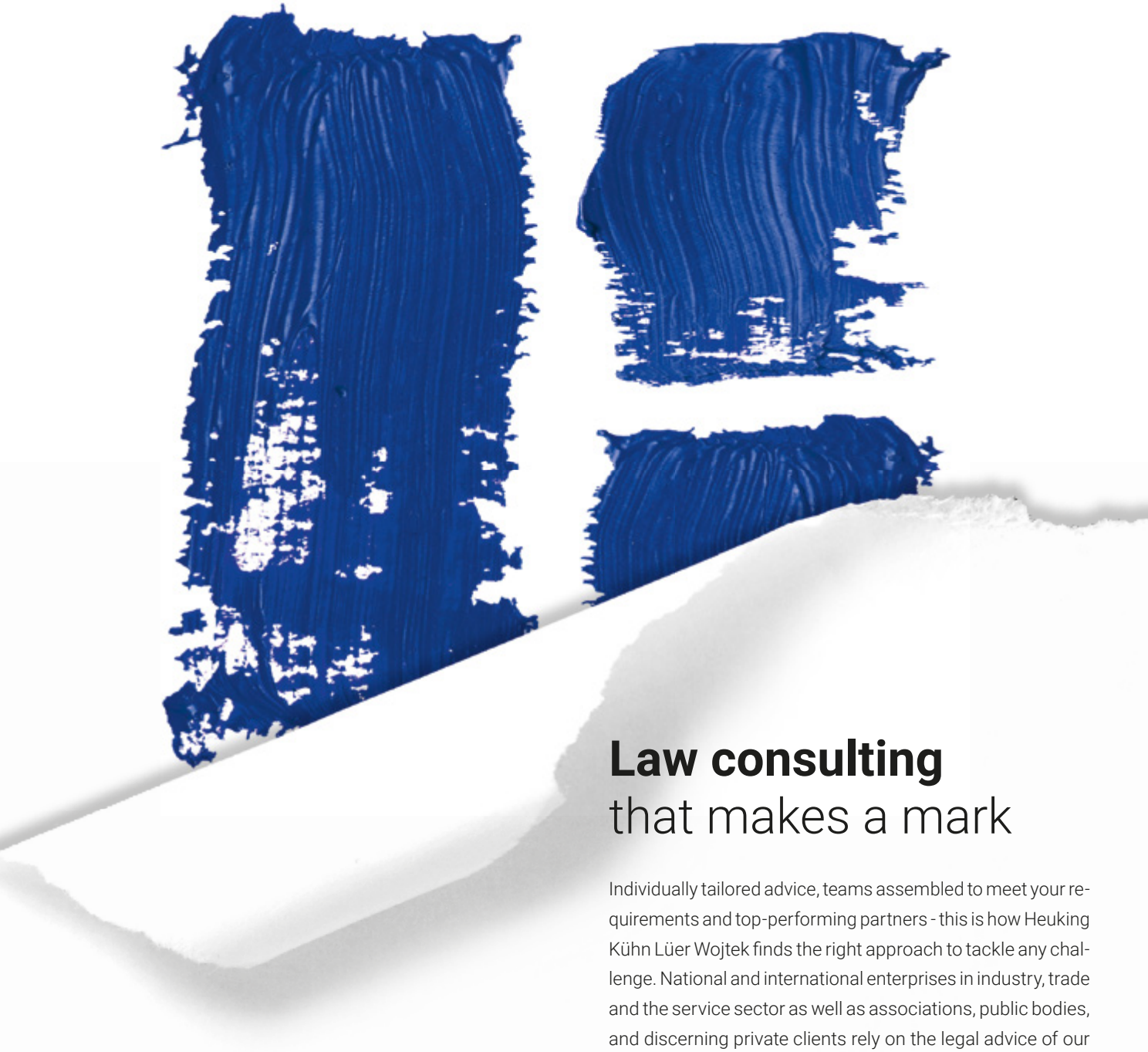

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01 REGULATORY, PRICING, AND REIMBURSEMENT OVERVIEW

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

• **Federal Ministry for Health (Bundesministerium für Gesundheit (BMG), Berlin and Bonn).** https://www.bundesgesundheitsministerium.de/
Drafting legislation, regulations and ordinances in all sectors of health care and social insurance, regarding admission of health care professionals, manufacturing and market licenses for medicinal products and medical devices.

• **Federal Agency for Medicinal Products and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM), Bonn.** www.bfarm.de/EN/BfArM
National manufacturing and market licenses for medicinal products and medical devices, authorization of clinical studies for medicinal products and medical devices, risk supervision, supervision of drug traffic.

• **Robert Koch-Institut (RKI)**
https://www.rki.de/EN/Home/homepage_node.html
The Robert Koch Institute (RKI) is the government's central scientific institution in the field of biomedicine. It is one of the most important administrative bodies for the safeguarding of public health in Germany. Intelligence, prevention, abatement and control of diseases, in particular infectious diseases.

• **Paul-Ehrlich-Institut (PEI)** https://www.pei.de/EN/home/node.html
The Paul-Ehrlich-Institute is another Agency of the German Federal Ministry of Health. Its research and control activities promote the quality, efficacy and safety of biological medicinal products. It is in charge of national market licenses for biomedical medicinal products such as vaccines, authorization of clinical studies and risk supervision regarding medicinal products.

• **Federal Insurance Agency (Bundesversicherungsamt, BVA)**
Supervision of federal public health insurers, administration of structural risk equalization between health insurers, health fonds.

• **Federal Center for Health Education (Bundeszentrale für gesundheitliche Aufklärung (BZgA)**
Prevention campaigns, education measures, model projects for child and youth health, aids, addiction.

• **Institute for Quality and Commercial Feasibility in Health Care (Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)**

Evaluation of diagnosis and therapy methods, cost and benefit evaluations for medicinal products. review of structured therapy programmes, high quality patient information.

• **Institute for Quality Security and Transparency in Health Care (Institut für Qualitätssicherung und Transparenz im Gesundheitswesen, IQTIG))**
Development and implementation of measures for quality enforcement and transparent reporting in health care.

Note on English language citations and summaries of German laws, statutes and regulations: As concerns English versions of the laws, statutes and regulations referred to in this publication, please refer to the translations made available on the following website of the Federal Ministry of Justice and Consumer Protection:
http://www.gesetze-im-internet.de/Teilliste_translations.html
References in this publication to English versions and summaries of German laws, statutes and regulations are partly based on the translations made available on above website.

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

1. Medicinal Products, Biologicals:

The regulatory framework for **German manufacturing and market authorizations** of medicinal products and biologicals is set forth in the **German Medicinal Products Act (also referred to as the Pharmaceuticals Act or Drug Act, Arzneimittelgesetz, "AMG") of 12 December 2005 as amended,** as well as a number of supplementary laws and regulations governing the implementation of the rules set forth in the Act. **An English translation of the AMG is available on the following website of the Federal Ministry for Justice and Consumer Affairs:** http://www.gesetze-im-internet.de/englisch_amg/index.html.

European manufacturing and market authorizations by EMA, London, are regulated by EU Regulations, notably Regulation (EC) No 726/2004.
Definition of **Medicinal Products**: Pursuant to § 2 (1) of the Medicinal Products Act, all "substances and preparations made from substances which are intended for use on or in the human or animal body and are intended for use, based on their properties, as remedies for the curing, alleviating or preventing of human or animal diseases or disease symptoms' are medicinal products (Medicinal Products), unless they are foods, cosmetics, tobacco products or medical devices. The rules of the German AMG are essentially based on EU Directive 2001/83 (Code of Human Medicines Directive), EU Regulation 536/2014 and many others.

2. Medical Devices:

The regulatory framework for the manufacture and authorization of medical devices is set forth in the Medical Devices Act (Medizinproduktegesetz, "MPG") of 2 August 1994, as amended, as well as supplementary laws and regulations governing the marketing of medical devices.

3. The regulatory framework of pricing of medicinal products and medical devices was reformed in 2011 and is essentially governed by the **Law Reforming the Pharmaceutical Market** generally referred to as "**AMNOG**" (**Arzneimittelmarkt-Neuordnungsgesetz of 2011**), as well as a number of other and supplementary laws and regulations. Up to 2011, the wholesale sale price of a new, patent protected prescription drug was determined by the manufacturer, except where such drug was assigned to a group of fixed price drugs. Since 2011, this applies only to the first year following market authorization. During that first year, any such medicinal product prescribed within the public health insurance system (Gesetzliche Krankenversicherung (GKV)) is evaluated as to its additional benefits as compared to other current standard therapies of the same indication (early benefit evaluation, „Frühe Nutzenbewertung"). If an additional benefit has been determined, the representatives of the GVK and of the manufacturer negotiate a reimbursement amount which is usually lower than the original manufacturer asking price. If there is no such additional benefit, the new drug is subject to a determined fixed price.

Wholesale adds a wholesale margin within a statutory maximum. That wholesale price is the nationwide uniform price charged to drug stores (pharmacies). The pharmacy sales price for prescription drugs (also uniform in Germany) is determined by adding a margin of 3 percent to the wholesale price, plus a fixed pharmacy service compensation of 8.35 Euros, and the value added tax. If the sale is charged to a public heath insurance, the price is reduced by a fixed deduction which is, since 2015, an amount of 1.77 Euros per unit.

The price of freely sellable medicinal products soled in pharmacies or elsewhere is determined by each pertinent seller (for example, herbal teas, plant extracts, vitamines, minerals etc.).

The price of the large number of generica is relatively moderate in Germany, whereas the prices for patent protected medicinal products is relatively high compared to other markets (where lower or no value added tax or different price regulation systems apply). The price difference prompts some German wholsale businesses to import from abroad (parallel imports).

4. The reimbursement of the cost of medicinal products and medical devices is regulated in laws and regulations regarding public health insurance and private health insurance. Details will be outlined in the answers to **questions 10 to 13** below.

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

1. The third section of the **Medicinal Products Act** (governing manufacturing licenses in §§ 13 to 20d), the fourth section (governing market license in §§ 21 to 37) as well as the sixth section (governing the protection of human subjects and ethincs in clinical testing in §§ 40 to 42b of the Medicinal Products Act) regulate the development, testing and marketing of **medicinal products.** The **Medical Devices Act** provides the corresponding background for medical devices. These statutes describe in detail the application and authorization process, withdrawals, revocations and the resting of the