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Austria
Life Sciences

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This country-specific Q&A provides an overview of life sciences laws and regulations applicable in Austria.

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Austria: Life Sciences

1. Please briefly summarize your country's legislative framework for medicinal products (including biologicals), medical devices, food, and food supplements

The life sciences sector in Austria is governed by a combination of national laws and European Union (EU) regulations.

Medicinal products (including biologicals)

Medicinal products are primarily governed by national legislation:

- Austrian Medicinal Products Act (Arzneimittelgesetz, AMG), which implements the EU Community code for human medicinal products (Directive 2001/83/EC) and related EU rules.
- Complementary legislation are the ordinance on operating rules for pharmaceutical establishments (AMBO), ordinance on medicinal products derived from human blood, the medicinal products import act (AWEG), and the medicinal product index regulation.
- Advertising and promotion: AMG complemented by the Unfair Competition Act (UWG) and industry codes (e.g. Pharmig Code).
- For biologicals and advanced therapy medicinal products (ATMPs), Regulation (EC) No 726/2004 (centralized procedure via EMA) and Regulation (EC) No 1394/2007 on ATMPs. The AMG complements these at the national level.
- Clinical trials are governed by EU Regulation 536/2014 and implemented domestically in AMG and the Hospitals and Medical Organizations Act (KAKuG).

Medical devices (incl. IVDs)

- Regulation (EU) 2017/745 (MDR) and Regulation (EU) 2017/746 (IVDR) are directly applicable.
- Austrian Medical Device Act 2021 (Medizinproduktegesetz 2021 – MPG), which supplements MDR/IVDR (e.g. advertising, language, enforcement, in house devices).
- National Ordinances: include Medical Device Operator Ordinance (MPBV) sets out rules for installation, operation, and use. Medical Device Reporting Ordinance: obligations to report incidents; Medical Device Levies Ordinance: Regulations governing levies to authorities; Magnetic Field Therapy Device Ordinance; Ordinance for HIV Self-Tests.

Foods

- Lebensmittelsicherheits- und Verbraucherschutzgesetz (LMSVG) – the Food Safety and Consumer Protection Act governs food safety, labeling, official controls, and enforcement in Austria. The Austrian Food Codex (Codex Alimentarius Austriacus) provides non-binding guidelines on definitions, compositions, and quality standards.
- EU legislation: Regulation (EC) No 178/2002 (General Food Law), Regulation (EC) No 852/2004 (food hygiene), food labeling follows EU Regulation 1169/2011, EU Food for Specific Groups Regulation (EU) No 609/2013 and a broad range of sector-specific EU regulations. Novel foods are regulated under EU Regulation 2015/2283

Food supplements

- LMSVG and national Food Supplement Ordinance Nahrungsergänzungsmittelverordnung – NEMV), transposing EU Directive 2002/46/EC which sets requirements for permitted substances (vitamins and minerals), maximum and minimum levels, labeling, and notification obligations.
- EU Health Claims Regulation, prohibiting any claims that the supplement can “prevent, treat, or cure" a human disease

2. With regards to medicinal products and medical devices, how is the regulatory process structured in your jurisdiction from R&D through market approval until post-marketing vigilance, and what rules does it follow? Please briefly describe.

The regulatory process and life cycle for health and food products follows a clear path from research to market, governed by both national statutes and harmonized EU regulations: EU harmonised rules for R&D and approval, with a central national body (BASG) from clinical trial authorisation through marketing authorisation to post marketing vigilance. BASG conducts market surveillance inspections, enforcement actions (recall, restriction, prohibition), imposes administrative sanctions/fines and can revoke authorizations.

Medicinal products

Drug R&D and Clinical Trials

- Non clinical work follows EU good laboratory practice and ICH standards.
- Approval: Sponsors submit via the EU CTIS portal. Clinical trials (Phases I–IV) must be approved by BASG. A positive vote from a (lead) Ethics Committee is required.
- Rules: Follows Good Clinical Practice (GCP) standards and the EU Clinical Trials Regulation (EU) 536/2014 (CTR) and AMG.

Drug Marketing Authorization (Market Approval)

- MA Types: Centralised procedure via EMA (mandatory for many biologicals/ATMPs); Decentralised or mutual recognition procedures involving Austria; AMG national procedure for products outside the centralised scope.
- Authorisations are typically granted for 5 years, after which renewal and benefit risk re assessment are required; variations and line extensions must be filed and approved under EU variations rules and their AMG implementation.
- BASG keeps the national register (Arzneispezialitätenregister) of authorised medicines and records all grants, changes and withdrawals.
- For biologicals, the same pathways apply, but regulatory guidance from EMA (e.g., biosimilar guidelines) sets additional requirements for comparability and immunogenicity data.

Drug Post-Marketing Vigilance

- Pharmacovigilance: The Marketing Authorization Holder (MAH) must maintain a system to monitor adverse reactions. The safety system follows Regulation (EU) 726/2004, Directive 2001/83/EC and GVP..
- Reporting: Serious adverse reactions must be reported to the EudraVigilance database.
- Inspections: BASG (together with AGES) conduct inspections to ensure the MAH is correctly monitoring and reporting risks, monitors benefit risk, evaluates safety signals, coordinates risk minimisation measures and can vary, suspend or revoke MAs.

Medical Devices (MD)

The framework is defined by the MDR/IVDR and the MPG:

MD R&D and Clinical Investigation

- Submission: Manufacturers must perform clinical evaluation or clinical investigations in line with MDR/IVDR; for device clinical investigations in Austria, applications are filed electronically with BASG, which validates and assesses them, again involving ethics committees as required.
- Technical Documentation: For all devices, a technical file including a clinical evaluation must be established during development.

MD Conformity Assessment (Market Access)

- CE Marking: The manufacturer issues a “Declaration of Conformity" and affixes the CE mark. For higher-risk classes (IIa, IIb, III), an independent private body (Notified Body) must audit the quality system and technical file.
- Registration: Devices and economic operators (manufacturers/importers) must be registered in the Austrian Medical Devices Registry and the EU database EUDAMED.
- MPG and national ordinances cover aspects such as language requirements, registration/notification obligations, advertising and some organisational provisions for notified bodies and healthcare institutions.

MD Post-Market Vigilance

- Post-Market Surveillance (PMS): Manufacturers must operate post market surveillance systems and report serious incidents and field safety corrective actions via the channels foreseen in MDR/IVDR.
- Vigilance Reporting: Serious incidents or “Field Safety Corrective Actions" (recalls/fixes) must be reported to BASG immediately.

3. What is the regulatory process for food supplements, from first notification to the competent authorities until post-marketing vigilance in your country, and what regulations are applicable here? Please briefly describe.

Generally, there is no pre marketing authorisation but a mere notification requirement for food supplements; operators place compliant products on the market under their own responsibility and are then subject to official food control and enforcement.

Core legislation

- LMSVG – national framework food safety, hygiene, and inspections
- Regulation (EC) No 178/2002 (EU General Food Law)
- Directive 2002/46/EC (Food Supplements Directive) and Austrian Food Supplements Ordinance (Nahrungsergänzungsmittelverordnung – NEMV):
- Regulation (EU) No 1169/2011 (Food Information to Consumers – FIC) sets general labeling requirements (allergens, nutrition, etc.).
- Regulation (EC) No 1924/2006 (Nutrition and Health Claims)
- Regulation (EC) No 1925/2006 (Addition of vitamins and minerals)

Additional EU rules apply where relevant (e.g., Novel Food Regulation (EU) 2015/2283, contaminants regulation, etc.).

Classification & Notification

Before entering the Austrian market, it must be determined whether a product qualifies as a food supplement (FS) under the NEMV, or whether it falls into another regulatory category such as a medicinal product, novel food, or fortified food. This classification question is critical as products containing vitamins, minerals, botanicals, or other bioactive substances at higher concentrations may be borderline with medicinal products and subject to reclassification by BASG or the food authorities. The AMG contains a medicinal product presumption that can override food classification where a product has pharmacological, immunological, or metabolic effects.

FS are subject to a mandatory notification procedure with the Health Ministry (BMSGPK) and scientific review support is provided by AGES. The notification must occur at the latest when the product is first placed on the Austrian market. The manufacturer or importer must submit a notification form along with a sample of the product's label. This is done via an electronic system. Receipt of the notification does not imply the product is “safe” or “approved”—legal responsibility remains entirely with the food business operator.

Novel ingredients: If a food supplement contains an ingredient that was not in significant use in the EU before May 1997, it may qualify as a novel food under Regulation (EU) 2015/2283, requiring prior authorization via the European Commission before it can be used.

Marketability Evaluation

In order to avoid legal and regulatory risks, companies may request a Marketability Report (Verkehrsfähigkeitsgutachten) from AGES (Austrian Agency for Health and Food Safety) or a private authorized expert. This report assesses whether the ingredients (e.g., specific herbs or novel foods) and labels comply with the LMSVG and NEMV.

Labelling and Health Claims

The notification must include the name and address of the operator, the product name, a specimen of the label, and the full list of ingredients including the amounts of active substances per recommended daily dose. Notifications are submitted in writing or electronically to the BMSGPK (a Health Ministry). The BMSGPK maintains a register of notified food supplements.

In addition to the general food labelling rules (LMIV/FIC), food supplements must carry specific mandatory indications, as reflected in the Austrian laws and AGES guidance. Labels must include the product name and designation as a food supplement, the names of the nutrient categories or substances characterizing the product, the recommended daily dose, a warning not to exceed the recommended daily dose, a statement that supplements should not replace a varied diet, and a statement to keep out of reach of children.

Any claims made on food supplements must be authorized under Regulation (EC) 1924/2006 and appear on the EU Register of authorized claims. Disease risk reduction claims and claims referring to children's development require specific authorization. Unauthorized or misleading claims are prohibited and subject to enforcement action.

Post-Marketing Vigilance & Control

Because there is no pre market approval, the system

relies on structured official control and self monitoring once products are on the market.

- Under the LMSVG, operators must maintain traceability at all stages, run appropriate self monitoring systems, and take measures (withdrawal/recall, corrective actions) if they identify risks.
- Authority control measures include: Sampling and laboratory testing, review of advertising and health claims, assessment of borderline classification (food vs medicinal product), contaminant and ingredient checks, monitoring of online sales
- Inspections: Provincial authorities (Lebensmittelaufsicht) perform unannounced inspections at retail sites, warehouses, and production facilities.
- Sampling: AGES routinely takes samples from the market to test in laboratories for: laboratory analysis & scientific risk assessment (composition, contaminants, adulteration (searching for illegal pharmaceutical ingredients)
- Vigilance: If a product is found to be harmful or misleading, the authorities issue a public warning or recall. Serious incidents are reported through the EU-wide RASFF (Rapid Alert System for Food and Feed).
- Sanctions: authorities may order relabelling, prohibit marketing, withdraw/recall products, impose administrative fines, or initiate criminal proceedings.

4. What are the ongoing obligations in your country after a marketing authorization for medicinal products has been obtained or a conformity assessment been carried out for medical devices?

In Austria, once a medicinal product is authorised or a medical device is CE marked, companies have ongoing obligations across safety/vigilance, quality and regulatory maintenance. The post-market obligations for medicinal products and medical devices are subject to continuous lifecycle management but differ in structure.

For both jealth products, the obligation to proactively monitor the benefit-risk profile and take corrective action rests squarely with the manufacturer or MAH, and failure to meet ongoing obligations can result in suspension or withdrawal of the authorization or certificate, product recalls, and significant regulatory and legal consequences.

Medicinal Products

Pharmacovigilance & Safety (AMG and EU GVP)

- Qualified Person: Operator must maintain a functioning pharmacovigilance system with a qualified person for pharmacovigilance (QPPV) and a Pharmacovigilance System Master File (PSMF). Austria law also recommends a local contact person for communication with the BASG.
- Responsible Person for trade Affairs: a regulatory compliance officer for drug trade law requirements must be appointed.
- Adverse Reaction Reporting: Suspected serious adverse reactions must be reported to the EudraVigilance database at EMA and to BASG (within 15 days) and non-serious ones within 90 days.
- Implement a robust quality management system for complaints, recalls and quality defects, including rapid notification to BASG of quality defects, batch withdrawals and supply disruptions where required

MA Maintenance

- Variations: Any change to the medicinal product (e.g., new manufacturing site, updated shelf life, or new side effects on the label) must be submitted as a variation under EU variation laws for approval.
- Renewals: Initial authorizations are valid for 5 years. A renewal application must be submitted to the BASG at least 9 months before expiry accompanied by a benefit–risk re evaluation.
- Sunset Clause: If a product is not actually placed on the market in Austria for 3 consecutive years, the authorization expires automatically.

Promotion & Supply

- Operator to ensure all advertising and promotion complies with scientific and rules under AMG and unfair competition advertising rules (no misleading claims, proper information to HCPs, restrictions on samples and benefits) and with industry and compliance codes.
- Supply Shortages: MAHs are legally required to notify the BASG of any temporary or

permanent cessation of supply or shortages that could impact patient care.

Medical Devices

Following CE marking under the MDR or IVDR, the manufacturer assumes ongoing obligations. BASG is the competent authority for market surveillance in Austria.

Post-Market Surveillance (PMS)

- PMS Plan & Report: Manufacturers must establish, document, implement and keep up to date a proactive and systematic PMS system proportional to the device risk class thus implementing a systematic process to collect and analyze data on quality, performance, and safety. For Class I devices, a PMS Report is required; for Class IIa and above, a more detailed Periodic Safety Update Report (PSUR) is mandatory.
- Post-Market Clinical Follow-up (PMCF): Implement a continuous process for higher risk classes to update the clinical evaluation throughout the device's lifecycle. Results are documented in a PMCF Evaluation Report, which feeds into the Clinical Evaluation Report (CER) and must be updated at defined intervals.

Vigilance & Reporting

- Incident Reporting: Manufacturers and, where relevant, authorised representatives/importers must report serious incidents and field safety corrective actions (FSCA) to BASG. Any serious incident occurring in Austria must be reported via the MIR form within strict timelines (e.g., 15 days, or 2 days for public health threats).
- Field Safety Corrective Actions (FSCA): If a manufacturer takes a technical or clinical measure to prevent risks (e.g., a recall), they must notify BASG and issue a Field Safety Notice (FSN).
- Clinical Evaluation Reports (CER) must be actively maintained and updated throughout the product lifecycle, reflecting new clinical data, post-market findings, and any changes to the benefit-risk profile.

Administrative Requirements

- EUDAMED/Registry: Operators (manufacturers, importers, distributors) must keep their data current in the EU database EUDAMED and the Austrian Medical Devices Registry.
- Person Responsible for Regulatory Compliance (PRRC): Every manufacturer must have at least one person responsible for ensuring the company meets these post-market obligations.
- Registration & Traceability: registrations and UDI system compliance, economic operator registrations (manufacturer, importer, authorised representative) and retention of documentation (typically 10–15 years depending on class)
- Maintain a quality management system meeting MDR/IVDR and applicable standards (typically EN ISO 13485), including ongoing technical documentation updates, Notified Body surveillance audits (for higher classes), processes for complaint handling, CAPA, recalls and field actions.
- Comply with Austrian law requirements such as language requirements for user information, advertising rules, “in house” devices.

5. Which are the competent national authorities having the regulatory oversight over medicinal products, medical devices, food, and food supplements and what are their respective responsibilities?

Regulatory oversight in Austria is mainly shared between a Health Ministry (BMSGPK) that handles high-level policy and sovereign decisions, and technical agencies that manages day-to-day operations and scientific evaluation, namely the Federal Office for Safety in Health Care (BASG) and the Austrian Agency for Health and Food Safety (AGES), with the Länder (reginal state) authorities playing a key role in food control.

Health Ministry (BMSGPK)

The Federal Ministry of Social Affairs, Health, Care and Consumer Protection (BMSGPK) is the supreme authority and serves as the overarching policy and supervisory authority. However, some food competences (e.g., food production) are shared with the Austrian Ministry of Agriculture.

- Role: The Health Ministry oversees the entire life sciences legal framework and acts as the ultimate decision-maker for policy, legislation, and international representation.
- Specific Responsibilities: o Medicinal Products and Devices: Sets legal and regulatory frameworks (ordinances, guidelines) and oversees the BASG. o Food/Supplements:

Direct responsibility for food safety legislation and the notification of food supplements. o Pricing: Handles the pricing of medicinal products (Pharmaökonomie).

BASG

The Federal Office for Safety in Healthcare (BASG) is a subordinate authority of the Health Ministry, acting as the executive arm for health products.

- Role: It executes official government tasks that require legal authority (sovereign acts).
- Key Responsibilities: o Medicinal Products: Issuing or revoking marketing authorizations, approving clinical trials, and enforcing pharmacovigilance. o Medical Devices: Monitoring the market (surveillance), managing the medical device register (together with the National Public Health Institute . Gesundheit Österreich GmbH), and handling MD-vigilance (incident reports). o Inspections: Authorizing and inspecting manufacturing sites (GMP) and distribution channels.

AGES

The Agency for Health and Food Safetc (AGES) is a state-owned agency that, in enforcement practise, provides the technical and scientific expertise required by the Health Ministry and BASG.

- Role: AGES operates the laboratories and performs the scientific assessments that underpin regulatory decisions.
- Key Responsibilities: o Medical Market Surveillance (AGES MEA): Provides the staff and infrastructure for BASG. AGES conducts the scientific review of dossiers for new medicines. o Official Medicines Control Laboratory (OMCL): Tests the quality of medicines, including batch release for vaccines and blood products. o Food Safety: Conducts risk assessments, laboratory testing of food samples, and manages the "One Health" approach (linking animal and human health). o Supplements: Analyzes supplement samples to check for illegal ingredients (e.g., undeclared drug substances) or excessive vitamin levels.

Provincial States and Authorities (Landeshauptmann)

While federal agencies set the rules for foods and supplements, the nine Austrian provincial states play a critical role in local food law enforcement.

- Local executive enforcement for food safety.
- Carrying out on-site inspections of food businesses, restaurants, and retail outlets to ensure compliance with the LMSVG.

Others:

- Federal Office for Food Safety (BAES): Focuses on agricultural inputs (e.g., seeds, pesticides, fertilizers), approvals, certifications, and monitoring for plant and animal health; acts as risk manager in these areas.
- Federal Office for Consumer Health (BAVG): In particular for food supplements it issues official certificates for exports, oversees internet-sourced supplements in collaboration with customs, and handles controls for consumer protection.

6. Please briefly describe the procedure of challenging regulatory decisions (e.g., denial of marketing authorization) made by the competent regulatory authority in relation to medicinal products, medical devices, and food supplements.

Generally, regulatory decisions in Austria are challenged through a structured administrative court procedure, with full judicial review available and escalation to the Austrian Supreme Courts on points of law. EU-level decisions must be challenged before special EU courts.

Medicinal Products and Medical Devices

The official decision is usually issued by the BASG. A complaint (Beschwerde) must be filed with the competent authority (BASG) within four weeks of the decision being served. This allows the authority to reconsider its decision through a preliminary decision on the complaint (Beschwerdevorentscheidung). The authority within 3 months can revoke or amend its own decision or uphild the original decision.

If the complaining party is still unsatisfied, they can request that the complaint be forwarded (Vorlageantrag) to the federal administrative court (BVwG). Where the immediate enforcement of a BASG decision would cause serious and irreparable harm, the applicant may apply to the BVwG for suspensive effect.

The court reviews the case de novo (facts, procedure and the legality). Proceedings before the BVwG can include

oral hearings and the submission of expert evidence. The court can either dismiss the complaint, amend the BASG's decision, or annul it and send it back to the BASG for a new procedure.

If a party finds that the court's ruling is based on an incorrect legal interpretation and/or violates their constitutional rights it can appeal the decision within 6 weeks before the Supreme Administrative Court (in case of an fundamental legal question) or the Constitutional Court.

If the decision stems from a centralised EU procedure (European Commission decision), an action for annulment before the General Court of the European Union (GCEU) under Article 263 TFEU can be lodged, with a further appeal to the Court of Justice of the EU (CJEU) on points of law.

For disputes involving private bodies such as Notified Bodies (e.g., certificate withdrawal), civil contractual remedies may also be relevant, depending on the case structure.

Food Supplements

Legal remedies will depend on whether the decision is a federal administrative act or a criminal administrative penalty (Verwaltungsstrafverfahren).

- Notification Denials: If the Health Ministry (BMSGPK) issues a formal decision prohibiting the marketing of a notified supplement, the appeal process is similar to the one described for drugs and devices, typically leading to the Federal Administrative Court.
- Local Enforcement: If a provincial authority (Bezirksverwaltungsbehörde) issues a penalty for non-compliance (e.g., health claims, market withdrawal or labeling), the appeal is filed with the respective Regional Administrative Court (Landesverwaltungsgericht – LVwG).
- If reclassification as a medicinal product occurs, competence may shift to BASG, and the federal court route applies.

7. Please briefly describe the legal framework and the relevant regulatory procedure (e.g., application process, requirements, approval, denial) that applies in your jurisdiction to clinical trials for medicinal products and medical devices.

In Austria, the legal framework for clinical trials has fully transitioned to the complex European Union systems with the medicinal products framework still being more procedurally and substantively harmonized than the medical devices framework. Generally, in both product domains BASG serves as the central national authority, ethics committee involvement is mandatory. Both systems follow the principles of prior regulatory control before trial start, mandatory ethics review, strict safety reporting.

Medicinal products (clinical trials)

- Framework: EU Clinical Trials Regulation (EU) 536/2014 (CTR), supplemented by AMG (§§ 29–36) and ICH-GCP, GDPR.
- Procedure: Sponsor submits full dossier via EU CTIS portal to BASG (validation within 10 days, ethics committee input); assessment (Part I: CT technical/safety/efficacy at EU level, Part II: ethics/national by Austria)
- Requirements: Full protocol, Investigational Medicinal Product Dossier, investigator's brochure, informed consent, insurance, GCP compliance.
- Any substantial modification must be submitted through CTIS and assessed
- Investigational medicinal products must be manufactured under a valid manufacturing authorization and in compliance with GMP; a clinical trial insurance or equivalent indemnification must be in place protecting trial subjects; informed consent must be obtained from all subjects in accordance with GCP and CTR.
- Approval/Denial: Single decision via CTIS within 60 days; appeal to federal administrative courts (outside CTIS). Mononational trials conducted only in Austria accelerated (up to 45 days). Tacit approval if no decision.

Medical devices (clinical investigations)

- Framework: EU MDR/IVDR (Arts. 62–82), supplemented by MPG (§§ 13–24) and ISO 14155 and GDPR.
- Clinical investigations are required for Class III devices and implantable devices unless the manufacturer can rely on existing clinical data demonstrating equivalence to an already CE-marked device; for other device classes, clinical investigations may be conducted voluntarily to generate clinical evidence supporting the clinical evaluation

- Dossier must include the clinical investigation plan (CIP), the investigator's brochure, the informed consent documents, the device description and technical documentation, evidence of GMP-equivalent manufacturing compliance, details of insurance arrangements, and a description of the clinical evaluation into which the investigation feeds.
- Procedure: Sponsor notifies BASG and ethics committee 60 days pre-start (electronic via BASG portal); parallel review (BASG: technical, Ethics Committee: participant protection); significant changes require new notification.
- Requirements: Clinical investigation plan, ethics vote, insurance, ISO 14155/GCP, risk analysis, informed consent.
- Approval/Denial: Explicit BASG authorisation needed; appeal via AVG to BASG then BVwG. Decision within 30-45 days post-submission (shorter for low-risk).

8. Is there a public database for clinical trials in your country, and what are the rules for publication?

Austria follows fully EU-harmonised transparency systems; there is no standalone national clinical trials database.

MEDICINAL PRODUCTS

Under the Clinical Trials Regulation (EU) 536/2014 all interventional clinical trials conducted in Austria must be registered in the public-facing EU Clinical Trials Information System (CTIS), operated by EMA, which replaced EudraCT and became mandatory for all new trials from January 2023. Registration must occur before the trial starts, and key trial information is publicly accessible via the CTIS public interface.

On results publication, EU Regulation 536/2014 imposes binding obligations on sponsors. A results summary in lay-friendly language (German) must be submitted to CTIS within 6-12 months of trial end (30 months for non-commercial sponsors). The full clinical study report must be submitted within 30 days of a marketing authorization decision. These obligations apply equally to all types of results. Public access includes protocol data, sponsor details, trial status, and results. Limited deferrals for commercially confidential information are possible.

MEDICAL DEVICES

For clinical investigations of medical devices, the relevant EU registration platform is EUDAMED, which features a dedicated "Clinical Investigations" module under MDR (EU) 2017/745. Registration and transparency requirements follow MDR Chapter VI. BASG is the competent authority and must authorize clinical investigations before they commence, with ethics committee involvement required in parallel. A full report and a mandatory layperson summary must be made public; this must generally happen within 12 months of the investigation's completion.

9. Please briefly summarize the rules that must be observed in your jurisdiction when using data from clinical trials?

In Austria, the use of clinical trial data for medicinal products and medical devices is governed by EU regulations (GDPR, CTR, MDR, IVDR) and national laws such data protection laws, AMG as well as MDR, or the national Research Organisation Act (FOG). These rules focus on three pillars: individual protection, transparency, and scientific utility.

Basic rules

- Legal bases: Processing of trial participants' health data generally requires explicit informed consent (Art. 9 GDPR); required in trial informed consent forms under AMG and MPG, or scientific research "broad consent" exemption under GDPR and FOG (§2d) for broad/secondary research use with safeguards) allowing data to be used for future research within broadly defined areas (e.g., "oncology research") rather than just one specific study, provided they are informed and the consent is voluntary
- Pseudonymisation/anonymisation: Data must be pseudonymized as early as possible. In Austrian trials, personal data (names) are replaced by codes and keys to these codes must be stored securely and separately. Data minimisation, purpose limitation and DPIAs required for high-risk processing.
- Secondary use: data collected for a trial can be reused for other scientific research purposes if under DPA or FOG (research privilege) under certain conditions. Further, integration with the EHDS will facilitate the cross-border secondary use of clinical data for research, provided specific "data permits" are obtained from a national access body.

Medicinal products

- Data Use and Reliability: Data must be robust, verifiable, and generated per Good Clinical Practice (GCP) standards for trial phases (I-IV) to support efficacy, safety assessments, and marketing authorizations. Non-compliant data (e.g., from unregistered trials) cannot be used in evaluations. For non-interventional studies (NIS), data use is limited to authorized products per SmPC, without additional patient burdens.
- Submission and Transparency: Data submissions to BASG/ethics committees for approvals; results (summaries and reports) must be reported within one year post-trial via EU portals (CTIS) for public access, excluding personal data. NIS data submitted to ethics committees only.
- Handling and Archiving: Data must be accurately recorded, processed, and stored to ensure interpretability and confidentiality; archived in a trial master file for at least 25 years post-trial, accessible to authorities like BASG

Medical devices specifics

- Data Use and Reliability: Data must support conformity assessments (e.g., for higher-risk classes IIa-III); non-compliant data (e.g., from unreported studies) cannot be published, shared (paid or free), or used in assessments. For post-market clinical follow-up (PMCF) or other studies, data use depends on therapeutic/diagnostic impact.
- Handling and Archiving: Data handled per MDR (Articles 61-82), with robust documentation for BASG inspections; archived to ensure verifiability and ongoing oversight.
- Submission and Transparency: Investigations with clinical impact require BASG approval (including ethics opinion); others need 30-day notification. Data submitted via electronic forms; results contribute to EUDAMED for public access, excluding confidential/personal info.
- MDR (Art. 10) requires PMS data handling per ISO 14155.

10. Are there any trends and/or legislative proposals in your country on digitizing the process of conducting clinical trials (e.g., digitalization of the application process, decentralization of clinical trials)?

Austria is following EU digitalisation mandates (such as CTIS) for clinical trials and is influenced by EU-wide trends toward decentralised trial practices. Specific national legislative proposals on broader digital or decentralised clinical trials have not yet been adopted, but policy discussions and EU guidance indicate growing emphasis on digital transformation in the clinical research landscape.

This includes the application portals which are already fully digital via CTIS (Medicines) and via EUDAMED (Devices). Approval speed is to be accelerated (FAST-EU) targeted at below 50 days. Further, electronic informed consent (eIC) is permitted by electronic signature (Qualified Electronic Signature) and remote monitoring is permitted within hybrid/decentralized trial frameworks.

11. What are your country's legal requirements for the authorization of manufacturing plants for medicinal products, medical devices, food, and food supplements? Please briefly describe.

In Austria, the authorization of manufacturing plants is divided between high-risk medical products (medicinal products and medical devices) and consumer-focused products (food and supplements). Also, in addition to specific product manufacturing licenses, specific trade licenses and plant permits must be obtained. The primary regulatory bodies are BASG/AGES and trade authorities.

Medicinal Products

Manufacturing plants require a drug manufacturing authorization (MDA/operating licence) from BASG under AMG. The applicant must detail the manufacturing activity's nature, scope, and location; premises, furnishings, and equipment; technical equipment; and appoint a qualified, experienced Qualified Person (QP). Compliance with Good Manufacturing Practice (GMP) principles is mandatory, aligned with EU guidelines, including use of GMP-compliant active substances.

Additionally, a regulated trade license (drug manufacture) as well as an operational plant/facility permit issued by the competent trade authority are required for manufacturing and storage, involving data on safety for life/health of employees and neighbors, plant description, equipment list, plans, technical details, and waste management. The authorization is granted for an unlimited period, but changes must be notified and permitted.

Medical Devices

Unless an ordinance for a specific device type exists, no specific pre-market manufacturing authorization is required from BASG. Compliance is ensured through ISO 13485 QMS, MDR/IVDR and the MPG, requiring manufacturers to implement a quality management system (QMS) certified by a Notified Body for higher-risk classes (IIa-III).

However, manufacturing business requires a trade license (MD manufacture) as well as an operational plant permit under trade regulations. Manufacturers based in Austria must also register in the national medical device registry, and custom-made device manufacturers have additional registration obligations.

Food

Manufacturing plants do not require specific food manufacturing authorization. However, they must register as food establishments under LMSVG and the Ordinance on Registration and Certification of Food Establishments, aligned with EU Regulation (EC) 852/2004 on food hygiene. Operators must implement hazard analysis and critical control points (HACCP), ensure traceability, and comply with hygiene standards across the food chain.

Additionally, a trade license (unregulated, no specific qualification required) must be obtained. An operational plant permit is required for industrial facilities, including details on safety, equipment, plans, and waste management. AGES and federal provinces oversee inspections and enforcement, with no separate authorization for plants but mandatory self-controls and official monitoring.

Food Supplements

Food supplements regulated under the LMSVG and the Food Supplements Ordinance (NEMV) do not require specific manufacturing authorization or product notification.

However, trade licenses and plant permits follow the same requirements as for food. Plants must maintain HACCP system, food hygiene standards, safe composition (e.g., maximum vitamin/mineral levels), labeling per FIC Regulation. Oversight by AGES and federal provinces focuses on safety and claims under EU Regulation 1924/2006, with self-responsibility on operators for safety compliance. High-risk operators (e.g., novel ingredients) face targeted controls

12. Please briefly describe the typical process of distributing medicinal products, medical devices, and food supplements in your country, encompassing, if applicable, the wholesale distribution of products.

The distribution of all three product categories follows EU rules with some national add ons: The complexity of the rules depends on the risk profile whereby medicines are the most tightly regulated, food supplements the least commensurate with their respective risk profiles.

Medicinal products

- Distribution requires a wholesale distribution authorisation (WDA) from BASG and permits from trade authority as well as compliance with EU Good Distribution Practice (GDP) guidelines; export counts as wholesale and also needs such authorisation; parallel imports require specific regulatory approval. Manufacturers do not require a separate WDA for products they produce themselves.
- Distribution Channels: Direct-to-patient delivery by wholesalers is prohibited. Authorised wholesalers can purchase from manufacturers or other authorised wholesalers and supply only to other wholesalers, public pharmacies, hospital pharmacies and certain healthcare institutions; supplying wholesalers from pharmacies is generally not allowed.
- Public pharmacies and hospital pharmacies then dispense to patients based on prescriptions or OTC rules, under the national pharmacy legislation and AMG.
- Verification (Serialisation): Under falsified medicines laws, wholesalers must connect to the Austrian Medicines Verification System (AMVS). All prescription medicinal products must bear a unique identifier (2D barcode) and tamper-evident seal
- Online sales of OTC medicinal products are permitted subject to strict conditions. Online sales of prescription medicinal products to patients are prohibited.

Medical devices

- Registration: Manufacturers, importers, authorised representatives and assemblers placing devices on the Austrian market must register in the Austrian Medical Devices Registry until EUDAMED is fully functional.
- Distribution channels depend on device class

and intended use. No pharmacy monopoly exists and Class I devices in particular can be sold through general retail channels. Channels include physicians, specialist medical dealers, hospital procurement systems, pharmacies (for lower-risk devices such as glucose meters, wound care products, and contraceptives), and online platforms.
- Online sales are permitted but subject to the MDR and Trade Code obligations for economic operators.
- Verification: Importers and distributors can only move CE marked devices through the supply chain when ensuring that devices bear CE marking, UDI, correct labelling (incl. German language) and are stored/transported without compromising compliance. Importers have additional verification obligations.
- Traceability: Distributors must be able to identify the party they supplied and from which supplier they received a device for at least 10 years (15 years for implantable devices).
- Taxes/levies: Any natural or legal person providing devices to end users in Austria must submit an annual fee declaration to BASG under the Medical Device Levy Regulation.

Food supplements

- No product notification but rregistration as food business operator for first placing on the market under LMSVG triggering inclusion in the official food control system and eligibility for Länder inspection authority oversight.
- Manufacturers/importers place products on the market under their own responsibility, then distribute via wholesalers, pharmacies, drugstores, supermarkets and online retail.
- Operators must ensure compliance with LMSVG, NEMV and EU food law (labelling, language, claims, composition) throughout the chain and with HACCP, traceability and hygiene requirements.
- Distance Selling: Online distribution (especially from abroad) is permitted but monitored by the Federal Office of Consumer Health (BAVG) to prevent the sale of supplements containing illegal pharmaceutical ingredients.

13. Please briefly describe the pricing and reimbursement rules, if any, for medicinal products, medical devices, and food supplements in your jurisdiction?

Medicinal Products

Austria operates a centralized pricing system with mandatory external price referencing for prescription medicines, and a structured reimbursement process through the national Reimbursement Code List (Erstattungskodex – EKO) requiring demonstration of therapeutic value and cost-effectiveness. OTC medicines have free pricing but limited reimbursement.

• **Pricing:** Austria operates a strict statutory price control system for prescription medicines: a Health Ministry sets maximum prices and manufacturers must notify prices to BASG. Austria references prices from EU member states such as Germany, Denmark, Netherlands, France, UK, Belgium (External Price Referencing – EPR). Maximum factory gate price (ex-factory price) is calculated as average of lowest prices in reference countries. A "Price Link Policy" for generics and biosimilars applies: The first generic drug must be priced significantly lower (typically ~50%) than the originator. Similar mandatory price reductions apply to biological follow-on products. Further, regressive mark-ups for wholesale and pharmacy apply: margins are capped by law using a regressive scale (the higher the product price, the lower the percentage mark-up).

• **Reimbursement by entry in the EKO is highly regulated:** Essentially, the applicant (drug distributer) must submit an EKO registration application for an authorized drug to the social security carrier which is assessed by a special evaluation commission (HEK) via economic and clinical criteria such as therapeutic benefit (added value vs comparator), medical necessity, cost-effectiveness, budget impact, availability of alternatives. Health economic analysis is required for innovative products claiming additional benefit.

EKO is structured as a box system: Standard Green Box (fully reimbursed; can be prescribed by any doctor without prior approval), Yellow Box – restricted (reimbursed only for specific indications/patients (whereby the EKO further distinguishes between dark and light yellow sub-boxes, with prior approval or ex-post audit), the pending Red Box (temporary status for new drugs under evaluation max 180 days – which requires prior approval) and the black "No-Box" for non-listed drugs (generally not reimbursed unless a "chief physician" at carrier grants an exception for individual clinical necessity) .

If the indicial assessment by HEK is positive, reimbursement price negotiations occur between the

manufacturer and the social security carrier. Pricing Arrangement such as price-volume agreements, managed entry agreements stipulating volume caps/confidential rebates or pay per performance-schemes/risk-sharing models (increasingly used for high-cost specialty medicines) are common. The officially published price may differ from the net effective price due to confidential agreements. Periodic re-evaluation by HEK may later result in price reductions, box reclassification or delisting.

The insurance carrier decides on inclusion in EKO and reimbursement category and publishes decision in EKO typically 6-12 months from application. Special reimbursement rules exist for orphan drugs, hospital-only medicines and off label uses.

Medical Devices

• Pricing for medical devices follows free-market principles with no statutory price controls or external reference pricing. Prices are typically negotiated between manufacturers/suppliers and the social insurance institutions. Industry framework agreements often define maximum reimbursable amounts. Austrian social insurance carriers (e.g., ÖGK, SVS, BVAEB) individually negotiate their own contracts and price tariffs with manufacturers or medical supply stores.

• Reimbursement is decentralized: For devices like wheelchairs, hearing aids, or blood glucose monitors, there is no reimbursement code or list comparable to EKO. Certain medical devices (like orthoses, prosthetics) are covered by social health insurance (e.g., ÖGK) if categorized as medical aids or as an assistive devices (Heilbehelfe/Hilfsmittel) upon medical prescription/approval, often with patient co-payments. Medical aids serve to cure, alleviate, or prevent the worsening of an illness, devices replace missing body parts or support impaired bodily functions. Medical necessity, therapeutic benefit, Cost-effectiveness and availability of comparable alternatives factor into reimbursement decision. Inpatient/outpatient procurement occurs via contracts/tenders between insurers and providers.

Food Supplements

• **Pricing:** There is no price regulation for food supplements. Manufacturers and retailers (pharmacies, drugstores, supermarkets) are free to set their own prices based on competition.

• **Reimbursement:** As a general rule, social insurance does not reimburse food supplements as they this product category is not considered “necessary medical treatment" under reimbursement laws (ASVG). Still, in rare, medically justified cases (e.g., severe clinical malnutrition or specific metabolic disorders where a supplement acts as a “medical food"), a health fund or private insurance might cover the cost upon individual application and medical approval.

14. What legislative framework applies to the advertising for medicinal products, medical devices, and food supplements in your country?

Advertising for health-related products is strictly regulated primarily via sector-specific laws suchas AMG and MPG, with the Unfair Competition Act (UWG) applying subsidiarily to protect public health and prevent consumer deception. No prior authority approval is required.

Across all three product categories the overarching principle is that advertising must be accurate, evidence-based, consistent with the authorized or intended use of the product, and must not mislead consumers or healthcare professionals as to the product's properties, safety, or efficacy. The most stringent rules apply to medicinal products, reflecting their therapeutic nature and the public health risks associated with inappropriate use, while food supplement advertising is primarily constrained by the health claims regulation which effectively prohibits the most commercially attractive claim categories absent EU-level scientific authorization.

Medicinal Products

The primary legal basis is the AMG supplemented by UWG and industry codes. Supervision is exercised by BASG or even industry associations; competition law enforcement may also occur via civil courts. Key requirements:

• **Prohibition for Prescription Drugs:** Advertising prescription-only medicines to the general public is prohibited. Such advertising may only be directed at healthcare professionals (HCPs).

• **OTC Products:** Advertising to the public is permitted for non-prescription (OTC) drugs, provided the ads are objective, not misleading, and include mandatory side-effects warnings. Further advertisers may not exaggerate efficacy, suggest any guaranteed success, imply absence of side effects, not target children inappropriately and may not suggest that medical consultation is unnecessary

• **Scientific Consistency:** All advertising must be consistent with the approved SmPC. "Off-label" advertising (promoting unapproved uses) is generally illegal.

• **Self-Regulation:** industry codes such as PHARMIG Code of Conduct set ethical standards for members of the relevant industry association, particularly regarding transparency/disclosure obligations, interactions with HCPs, HCOs and patient organizations and the prohibition of gifts.

• Further, strict compliance rules are set out for promotional aspects such as medical events, hospitality, pre-approval-marketing, samples, medical sales representatives.

Medical Devices

A similar strict advertising framework exists for medical devices under the MPG and MDR/IVDR as well as industry codes:

- Misleading Ban: Article 7 of the MDR prohibits ascribing functions or properties to a device that it does not have, especially regarding intended purpose, safety, performance, CE marking status. Performance claims, particularly for IVD devices under the IVDR, must be consistent with the device's validated performance characteristics.
- Public Advertising Restrictions: Under the MPG advertising to the general public is prohibited for such devices that are subject to prescription or that are intended exclusively for use by HCPs, or are applied under the supervision (treatment-linked) of HCPs.
- Mandatory Content: Public advertisement must include the name, intended purpose, and a clear warning about potential adverse effects or safety precautions.
- Prohibited Elements: Advertisement cannot suggest a medical examination is superfluous, child-targeting or use pictorial representations of changes in the human body (e.g., "before and after" surgery shots).
- Special rules, e.g., on samples, are set out under industry codes, such as the AUSTROMED code.
- BASG monitors advertising compliance as part of its market surveillance activities under the MPG. The UWG provides a parallel civil law enforcement mechanism through which competitors, consumer organizations, and industry bodies may seek injunctions and damages before civil courts for misleading or unfair device advertising.

Food Supplements

Advertisement rules are laid down in particular under LMSVG/NEMV and the EU Health Claims Regulation (1924/2006) and FIC Regulation (1169/2011). Enforcement lies primarily with provincial food authorities and AGES monitors the market; unfair competition actions are possible.

- Approved "Health Claims": only health claims may be used that are explicitly authorized in the EU Register of Health Claims (e.g., "Vitamin C contributes to the normal function of the immune system").
- Ban on Disease-Related Claims: Claim that a food supplement can prevent, treat, or cure a human disease are prohibited (e.g., "cures joints" or "prevents cancer"). Any advertising claim attributing therapeutic, curative, or disease-preventive properties to a food supplement may trigger reclassification as an unauthorized medicinal product under the AMG.
- Prohibited Claims: Claims suggesting that health could be affected by not consuming the food supplement, claims referring to the rate or amount of weight loss, claims referencing recommendations by individual health professionals.
- Language & Clarity: Advertisement must be in German and must not set out exaggerated or unproven effects and must not imply that a balanced diet cannot provide sufficient nutrients.
- Transparency: Editorial content (in particular in "influencer"-marketing) must be clearly separated from advertising to avoid "stealth" marketing.
- Unfair competition rules under UWG provide a broad basis for challenging misleading food supplement advertising including exaggerated efficacy claims, misleading comparisons, and deceptive presentation.

15. What laws apply to patents and trademarks for medicinal products, medical devices, and food supplements in your country?

In Austria, the protection of IP for life sciences products is governed by national federal laws and harmonized EU regulations. In principle, these IP regimes are product-

neutral (i.e., not sector-specific), but certain pharmaceutical-specific mechanisms apply in the medicinal product field. The Austrian Patent Office (ÖPA) and the is the central authority responsible for granting and managing these IP rights.

Additional IP protection instruments relevant for these product domains are trade secrets (for biologicals manufacturing processes and food supplement proprietary formulations), design rights (distinctive device shapes and packaging aesthetics) or copyright (clinical trial reports, scientific publications, and promotional).

Patents

Patents protect technical inventions that are new, involve an inventive step, and are industrially applicable. The primary legislation are the Austrian Patent Act (Patentgesetz 1970) and the European Patent Convention (EPC).

- **Duration:** The maximum term is 20 years from the filing date. Products designated as orphan medicinal products benefit from 10-12 years of market exclusivity
- **Scope for Products:** o Medicinal Products: New active ingredients, formulations, processes and second medical uses (new therapeutic applications for known substances) can be patented. Biological medicinal products are patentable. The so called "bolar exemption" permits generic and biosimilar manufacturers to conduct studies and trials necessary for regulatory submissions. o Medical Devices: Patents cover the mechanical, electronic, or software-based innovations within the device. Software-based medical devices may require analysis under EPC rules on patentability of computer-implemented inventions. o Food supplements are patentable (process, formulation, novel ingredients) if technical invention demonstrated (not mere recipes). Naturally occurring substances per se are not patentable; many common supplement ingredients (vitamins, minerals, standard herbal extracts) are in the public domain. o Exclusions: Methods for the treatment of the human or animal body by surgery or therapy and diagnostic methods are not patentable in Austria.
- **Supplementary Protection Certificates (SPCs):** Under the EU SPC Regulation (and national Schutzzertifikatsgesetz), patent holders (especially of originator pharmaceuticals) can apply for an extension of up to 5 years for medicinal products (not available for medical devices, food supplements). A SPC Manufacturing Waiver permits generic and biosimilar manufacturers to manufacture SPC-protected products in the EU for export to third countries or for stockpiling Paediatric Extension: An additional 6 months can be granted if the product was tested according to an approved Paediatric Investigation Plan (PIP). EU Regulation (EC) 1610/96 further regulates SPCs for plant protection products.

Trademarks

Under the Austrian Trademark Protection Act (Markenschutzgesetz – MSchG) any sign capable of distinguishing the goods or services of one undertaking from those of others may be registered as a trademark, including words, logos, colours, shapes, sounds, and three-dimensional marks. Additionally EU-level instruments such as the Unitary Patent, EU Trade Marks (EUTM), and SPC Regulation are relevant. Trademarks are the primary brand protection tool for food supplement manufacturers given the limited availability of patent protection for common ingredients.

- **Duration:** Protection lasts 10 years and can be renewed indefinitely every 10 years.
- **Health-Specific Restrictions:** o Similarity: In the medicinal sector, the "likelihood of confusion" is assessed strictly to avoid a mix-up between two differently intended medicines. o Descriptiveness: Names that merely describe the effect or the ingredient (e.g., "Cough-Stop") are generally rejected as they must remain available for all competitors to use. o Approval Alignment: For medicinal products, the trademark must also be approved by the BASG/EMA as part of the naming process to ensure it doesn't mislead patients about the drug's properties. o The INN (International Nonproprietary Name) of an active substance cannot be registered as a trademark under MSchG and EUTM Regulation: INNs are in the public domain and must remain freely available for use by all manufacturers. o Trademark owner cannot use trademark rights to prevent parallel importation of branded products first placed on the market in another EEA member state by or with the consent of the trademark owner (exhaustion of rights). Still, parallel importers of medicinal products who repackage or relabel products must comply with strict

conditions including prior notice to the trademark owner, clear identification of the repackaging party, and maintenance of product quality.

16. Please briefly describe how patent infringements in relation to medicinal products and medical devices are addressed in your jurisdiction, including possible defense strategies and legal proceedings against patent infringements.

Patent infringements for medicinal products and medical devices are addressed through a dual-track system: on the one hand, the national court route and, on the other hand, the increasingly dominant Unified Patent Court (UPC) for European patents. Austria's patent enforcement framework offers patent holders robust civil and preliminary injunction remedies, while defendants benefit from a range of invalidity and non-infringement defenses. The emergence of the UPC as an alternative and complementary forum has added significant strategic complexity to pharmaceutical and device patent litigation in Austria, making early forum selection analysis (e.g. bifurcation, preliminary injunctions) an essential component of any life sciences IP litigation strategy.

Legal Proceedings and Forums

- National Route: The Commercial Court of Vienna (Handelsgericht Wien) has exclusive jurisdiction over patent infringement cases in Austria. Appeals are handled by the Higher Regional Court of Vienna and the Supreme Court (OGH).
- Unified Patent Court (UPC): Since 2023, the UPC has jurisdiction over European patents with "unitary effect" and traditional European patents (unless opted out). Austria hosts a Local Division in Vienna. A Central Division in Milan specifically handles validity matters for pharmaceutical, medical device patents and human necessities. A single UPC decision can result in an injunction valid across more than ten European states outside of Austria.
- Criminal aspect: Intentional patent infringement can also constitute a criminal offence under the PatG, punishable by fines or imprisonment, though practice is mainly civil.
- Administrative proceedings relating to patent validity are handled by the ÖPA and its patent nullity division, with appeals to the courts. Austrian patent litigation is defined by a bifurcation of infringement and validity proceedings meaning that an infringer may be subject to an injunction even where a parallel validity challenge is pending, creating significant commercial risk – however, this does not apply to UPC procedures (which provide for a counterclaim option).
- The patent holder may also apply to Austrian customs authorities for border measures under EU Regulation 608/2013 on customs enforcement of intellectual property rights, enabling customs to detain suspected infringing goods at the Austrian border or at EU external borders. Border measures are particularly relevant for pharmaceutical products imported from outside the EEA that may infringe Austrian or EU patents or SPCs. Available Remedies
- Preliminary Injunctions (PIs): are critical in the life sciences cases to prevent generic entry or the sale of a competing medical device. These can secure injunctive relief, removal, damages and profit claims – PIs may be granted inter partes or, in exceptional cases, ex parte (e.g. risk of irreparable harm or evidence destruction); warning letters are not mandatory before applying. Courts are increasingly denying preliminary injunctions if the patent holder waits too long (typically more than a few months) after becoming aware of the infringement, citing a lack of urgency.
- Main Proceedings: Final relief (court decisions) includes permanent injunctions, damages (calculated as lost profits, reasonable royalty, or surrender of the infringer's profits), seizure/recall and destruction of infringing products, rendering of accounts, or publication of the judgmentand.

Common Défense Strategies

- Non infringement: The alleged infringer may contest that its product or process falls within the scope of the patent claims. (no literal or equivalent use of all claim features; design around). For medicinal products, generic companies often use "skinny labeling" (carving out patented indications from the product information) to argue they are not infringing a "second medical use" patent.
- Exhaustion of Rights: In the pharmaceutical parallel import context, exhaustion arguments are frequently raised where an originator seeks

to use patent rights to block parallel imports of its own branded products from lower-price EEA markets into Austria.
- License Scope: License scope disputes – particularly regarding field of use limitations, territorial restrictions, and sublicensing rights – are common in life sciences patent litigation and may be resolved through contractual interpretation proceedings before civil courts.
- Bolar Exemption: Allows competitors (e.g. generics, biosimilars) to conduct trials and studies for regulatory approval (marketing authorization, HTA, pricing) without infringing the patent.
- Prior Use Rights (good faith use): If a company was already using the invention in Austria before the patent was filed, they may have a right to continue that specific use.
- EPO Opposition Proceedings: Opposition proceedings, filed within 9 months of grant of a EU patent, are used in the pharmaceutical industry as a cost-effective mechanism for challenging broad originator patents before infringement disputes crystallize.
- Bifurcation of infringement and patent validity proceedings (Austrian courts).

17. Does your jurisdiction provide for restrictions on the use of trademarks for medicinal products, medical devices, food, and food supplements?

Yes, in Austria, the use of trademarks for medicinal products, medical devices, and food supplements is subject to significant restrictions so to prioritize public health, patient safety, and the prevention of consumer deception. Generally, trademark applications will be refused on absolute grounds (MSchG and EUTM Regulation) where the mark is generic, lacks distinctiveness, is contrary to public policy or accepted principles of morality, or is deceptive (efficacy, safety, or quality) as to the nature, quality, or geographic origin of the goods. Further, trademark applications conflicting with earlier registered marks (likelihood of confusion) will be refused or subject to opposition on relative grounds.

Medicinal Products

The restrictions here are the most stringent, as a trademark often serves as the "invented name" of a drug.

- International Nonproprietary Names (INN/WHO names) are reserved; trademarks identical/similar to INNs (stems) are rejected to avoid confusion with active ingredient's generic name. This applies to the INN stem system as well – marks incorporating recognized INN stems (e.g., "-mab" for monoclonal antibodies, "-tinib" for kinase inhibitors) may be refused if they create a likelihood of confusion with the INN. Biosimilars too must be clearly distinguishable from the reference product and from each other through their brand names, supporting pharmacovigilance traceability.
- Safety-Based Naming: EMA/BASG must approve the product name (look-alike/Sound-alike). A trademark will be rejected if it is misleading or confusing (visually, phonetically, or in script) with regard to existing medicines in particular in context with therapeutic claims or strength/dosage implications or medication errors. Post-authorization name changes may be required where safety incidents attributable to name confusion are identified.
- Prohibition of Promotional Claims: A trademark cannot contain promotional claims (e.g., "BestCure" or "SuperRelief") especially off-label claims, exaggerated efficacy/success or absence of risks. Further, a trademark must not suggest therapeutic properties the drug does not possess or imply a 100% success rate.
- EEA Parallel Import: Trademark use may be limited under EU exhaustion principles where products are repackaged or rebranded in parallel trade scenarios
- Symbol Restrictions: In official product information (SmPC/PILs), the use of the registered trademark symbols (® or ™) is generally prohibited to ensure the text remains clear, objective and strictly scientific. But on packaging (labelling), symbols may appear if they form part of the registered trademark and do not violate readability rules.

Medical Devices

There is no prior regulatory name approval system, but post-market enforcement is possible.

- Deception Ban: Article 7 of the MDR prohibits trademarks that create a false impression regarding the device's intended purpose, safety, or performance. For example, a name cannot imply a device is "risk-free" or "permanent" if it is not.
- Tademark must align with the technical documentation and conformity assessment. Product names must not falsely suggest

medicinal properties. Trademarks mimicking CE marks also get rejected, use of the CE mark in advertising in a manner suggesting third-party endorsement or certification beyond its regulatory meaning is forbidden.
- Alignment with UDI: The trademark must be consistent with the Unique Device Identifier (UDI) data registered in EUDAMED to ensure traceability. Brand name changes or variations require corresponding UDI database updates, creating a practical constraint on trademark management for device portfolios.

Food and Food Supplements

- Health Claims: Only permitted if trademark is supported by an authorized health claim from the EU Register. Brand names forming part of a product's presentation can constitute health claims.
- Disease-Related Prohibitions: A trademark for a food supplement cannot imply that the product prevents, treats, or cures a disease. This is stricter for food supplements due to borderline medicine risks.
- Marks must not suggest official approval, or mislead consumers about the composition or benefits, or create confusion with medicinal products.
- Mandatory German Language: While the trademark itself can be in English, all accompanying mandatory warnings and descriptions on the label in Austria must be in German.
- Certain botanical ingredients used in food supplements are subject to geographical indication protection , and supplement brand names that evoke protected origins without entitlement may conflict with these rights.
- Descriptive/Generic Names: As many supplement ingredients are well-known generic substances (vitamin C, omega-3, magnesium), the available trademark space is effectively limited to distinctive invented names, logos, and combinations.
- Misleading Marks: Brand names that mislead consumers as to the nature, composition, or properties of the product – including exaggerated implied efficacy – may be challenged under unfair competition laws.

18. Please briefly describe the product liability regime for medicinal products, medical devices, and food supplements in your country.

Austria's product liability framework provides injured parties with multiple overlapping legal bases for claims against manufacturers or EU-importers (and even suppliers), with strict liability as the foundation across all three product categories, supported by general tort law for fault-based claims.

Product liability for life sciences is primarily governed by the Austrian Product Liability Act (Produkthaftungsgesetz – PHG), the regime of which is based on strict liability, meaning a claimant does not need to prove negligence (fault), only that the product was defective and caused harm. Austria has not implement a specific financial cap on the total liability for a defect (though the PHG has a property damage threshold of €500).

Austria' product specific laws (e.g., AMG, MPG) do not set out specific product liability rules but define the standard as to what has to be considered a defect. Medicinal products and medical devices typically involve complex causation and expert evidence; food supplement cases more commonly concern contamination or labelling defects.

Defences and Limitations

- Development Risk: The producer is not liable if they prove the defect could not be detected by the scientific/technical knowledge at the time of launch.
- The defect did not exist when the product was placed on the market.
- The product was not put into circulation.
- The defect is due to compliance with mandatory regulations.
- Third-party instructions and consumer misuse.

Statute of Limitation

3 years from knowledge of damage, defect and liable party. An absolute cutoff of 10 years after the specific product was put into circulation (15 years longstop as from 2026/2027).

Medical Products

- Defect: Product lacks safety expected from presentation/marketing/use instructions (design, manufacturing, warning defects); side effects alone do not prove defect.
- Liability: Manufacturer/importer/supplier liable; claimant proves defect, damage, causation.

- Limits: No property-damage exclusion for personal injury. No cap for personal injury/death
- Potential Defect of Devices (Batch Liability): If a specific batch of medical devices (such as pacemakers) has a higher-than-normal failure rate, the entire batch may be legally classified as "defective," even if the individual device used by a specific patient has not yet failed.

Food Supplements

- Safety Standards: A supplement is defective if it contains excessive contaminants, undeclared allergens, prohibited substances (e.g., "novel foods" without approval or illegal drug analogues) or if the dosages are so high they are deemed harmful to health.
- Misleading Claims: If a supplement's trademark or label suggests a curative effect it doesn't have, and a patient suffers harm because they relied on the supplement instead of seeking medical treatment, this can trigger "instructional defect" liability.

Applies to life sciences products (medicines, devices, software/AI as "products"); MS must transpose by Dec 2026. Key updates:

Overview New Product Liability Rules 2026

Forthcoming EU product liability rules will substantially strengthen claimants' procedural and substantive positions across all categories, making proactive liability risk management – including robust pharmacovigilance, post-market surveillance, and product liability insurance – increasingly important for life sciences operators in the Austrian market.

- Expanded scope: Liability includes software (standalone, non-embedded), AI systems, chemicals and "related services" (e.g., cloud-based monitoring) and expands the scope of liable parties (economic operator, fulfillment providers).
- Defect definition: Product fails expected safety or safety requirements under EU/national laws (e.g., AMG, MPR), any violations leads to a defect presumption. "Defect" also includes software updates, cybersecurity, AI/machine learning.
- Burdeen of Proof/Disclosure: Claimant shows plausibility. Defendant must disclose evidence (or defect will be presumed).
- Presumption of Defect: a product is defective if (i) the manufacturer fails to disclose relevant evidence, (ii) the product does not comply with mandatory safety requirements (like AMG or MDR), or (iii) the damage was caused by an "obvious malfunction.
- Technical Complexity: If a claimant faces "excessive difficulties" due to technical or scientific complexity (highly relevant for AI-driven medical devices), the court may presume the defect or the causal link as long as the claimant shows that the defect/causation is likely.
- Damages also include data loss and psychological harm.
- Limitation: 15-year longstop

19. Please provide a short overview of risks of liability (criminal liability, serious administrative / civil liability) and enforcement practice with regards to medicinal products (including biologicals), medical devices, foods, and food supplements.

Austria follows a compliance-driven but safety-focused enforcement model. Administrative enforcement is the primary tool; criminal prosecution is reserved for serious misconduct. Essentially, liability exposure for life sciences operators in Austria arises across four distinct but overlapping tracks: criminal liability under sector-specific statutes and the Austrian Criminal Code (Strafgesetzbuch – StGB), administrative liability under the AMG, MPG, LMSVG, and related ordinances, and civil liability (e.g. cease and desist orders, damage compensation) under the PHG and ABGB or under unfair competition laws. Additionally, liability can arise out of obligations in industry codes provided that the operator is member of the relevant association (e.g., Pharmig or Austromed).

Enforcement is conducted by BASG/AGES, Länder food inspection authorities, the public prosecutor's office (Staatsanwaltschaft), and civil courts, with significant coordination between regulatory and prosecutorial authorities in serious cases. BASG conducts regular inspections and reacts quickly to safety signals and EU-level alerts. Cross-border coordination within the EU framework is common.

Administrative Liability (Regulatory Offences)

This is the most common form of enforcement for violations of medical product laws, such as AMG or MPG. The primary sanctions are fines and corrective measure

(including revocations of authorizations or business permits). Primarily liable are the management or appointed responsible persons for regulatory matters.

- Medicinal Products & Medical Devices: Violations of the AMG (e.g., illegal advertising, labelling, PV failures, missing side-effect reports) or MPG (e.g., distributing non-CE marked devices) are sanctioned with administrative fines. Fines can reach up to €25,000 (or €50,000 in repeat cases) per violation including mere attempts
- Food and Supplements: Violations of the LMSVG (e.g., using unauthorized health claims or incorrect labelling) are handled by District Administrative Authorities. Fines typically range from a few hundred Euros to €70,000. Cumulative fines (one fine per non-compliant product pack) are possible.

Criminal Liability

Criminal proceedings against an individual and/or a company are initiated by the public prosecutor if a violation poses a direct threat to life or constitutes fraud.

- Endangerment of Health: Intentionally or negligently bringing harmful medicinal products, devices or food into circulation can constitute (various) criminal offenses under the Austrian Criminal Code (StGB). This applies to cases of mere endangerment of the general public as well as in cases of actual bodily harm. Penalties can lead to heavy fines (based on daily net income) or imprisonment.
- Anti Bribery and Corruption: StGB sets forth a robust framework of ABC rules for bribery in the private and public sector as well as misuse of official power. Further, typical white collar crimes such as fraud or embezzlement are relevant. These crimes are supported by specific anti-gift and hospitality stipulations in the AMG, MPG and unfair competition laws.
- The LMSVG sets out that who places harmful food products, consumer goods or cosmetic products on the market is liable to imprisonment or a fine.
- Counterfeiting & Fraud: The AMG sets forth crimes for falsifying documents or selling counterfeit medicines.

Civil Law Claims

In practice, the most commercially impactful civil law tools in the life sciences sector are preliminary injunctions, cease and desist orders and publication of the final judgement under unfair competition laws (UWG) enabling rapid cessation of unlawful advertising or competitive practices. Furthermore, PHG/ABGB damage compensation claims for patient harm are relevant. Damages recoverable under civil law include actual loss (damnum emergens), loss of earnings (lucrum cessans), pain and suffering (Schmerzengeld), and future care costs, with Austrian courts applying established tariffs for pain and suffering compensation developed through case law.

20. Does your jurisdiction provide for a specific legislative and regulatory framework for digital health applications (e.g., medical apps)? If yes, please briefly describe the relevant framework.

Notwithstanding the amendments described below, there is no separate digital health statute for such applications yet, but medical apps are comprehensively regulated within the existing medical device and data protection framework: Digital health applications in Austria are regulated through a combination of directly applicable EU law (primarily the MDR) and a growing body of national e-health legislation/health telematics, reimbursement law, and data protection law. The regulatory treatment of any specific digital health application depends critically on its classification – whether it qualifies as a Software as a Medical Device (SaMD) under the MDR, a general wellness application (consumer laws, GDPR, no MDR but borderline claims may trigger reclassification as a medical device.), a clinical decision support tool, or a telemedicine service – as this classification determines which regulatory framework applies and what obligations follow. Reimbursement of SaMD and digital therapeutics in Austria is assessed within the existing benefits catalogue (Leistungskatalog) framework of the social health insurance system under social security laws (ASVG). Applications for reimbursement of SaMD as medical aids (Heilbehelfe) or assistant devices (Hilfsmittel) are submitted to the social security carrier (Dachverband der Sozialversicherungsträger), which assesses clinical effectiveness and cost-effectiveness.

Upcoming App on Prescription: Further, the regulatory landscape for digital health applications (DiGA—Digitale Gesundheitsanwendungen) in Austria transitions to an fully regulated DIGA prescription and reimbursement approach. The legislative goal is to have a fully operational, uniform assessment and reimbursement process by presumably early 2027, allowing HCPs to prescribe apps as part of standard care. To be prescribed and reimbursed in Austria, a medical app will have to

clear two distinct hurdles: The app must first be certified as a medical device under MDR (including safety, performance, and clinical evaluation standards). Most health apps fall into Class IIa or higher. Once CE-marked, the app must undergo a national evaluation by the social insurance association to be listed as “reimbursable." The criteria include: clinical benefit (e.g., improved health status, shorter therapy duration, or better patient adherence), technical quality (usability, data security, and interoperability to connect to the Austrian ELGA electronic health record) and cost-effectiveness.

21. Does your jurisdiction provide for laws or certain legal measures to ensure the supply of medicinal products and medical devices, or are such rules envisaged in the future? If yes, please briefly describe those rules.

Yes, Austria has established legal measures to ensure the supply of medicinal products (less so for medical devices), primarily through statutory duties, mandatory reporting and regulatory oversight by BASG, and additional measures in response to shortages, COVID-19, and EU-level supply security initiatives. The system is based on a mix of proactive stockpiling, export restrictions, and enhanced digital monitoring.

Medicinal Products

AMG imposes a statutory supply duty on marketing authorisation holders (MAHs), wholesalers and full-line wholesalers. These operators must ensure adequate and continuous supply to pharmacies and authorised dispensers to meet patient needs in Austria. Further, MAHs (and authorised representatives) under specific ordinances must notify BASG of any restriction in supply for prescription-only human medicines expected to last more than 2 weeks (or more than 4 weeks for insufficient availability), via eServices; voluntary for OTC unless GMP-related. BASG publishes an online list of shortages (https://medicineshortage.basg.gv.at), coordinates task forces and can impose case-by-case export bans for critical medicines; national stockpiling notifications for 2026 are required.

MAHs are required to maintain a four-month buffer stock of critical medicines in Austria. (including antibiotics, painkillers, and treatments for chronic cardiovascular and respiratory diseases). To prevent life-saving drugs from being siphoned off to higher-priced foreign markets, the BASG maintains a dynamic export ban Index when a product is flagged as being in “critical shortage” in Austria, the BASG can legally prohibit its export or “parallel trade". Austria is expected to align with upcoming EU pharmaceutical reform packages, introducing stronger EU-wide shortage prevention and reporting mechanisms.

Medical Devices

The supply security for medical devices is handled differently, focusing more on surveillance and diversification than on fixed local stockpiles. The focus lies on quality, market surveillance and the national medical devices register. Supply continuity relies on general market obligations under MDR/IVDR and competition law; no mandatory shortage reporting or export bans are currently planned.

22. Are there any specific compliance standards in your jurisdiction for the marketing of medicinal products and medical devices (e.g., codes of conducts of industry associations, etc.)? If yes, please give a brief overview of the relevant standards.

Self-regulatory compliance standards play a critical role in particular with regards to medicines and medical devices. Industry associations like the member codes issued by Pharmig and Austromed or EFPIA Code and the MedTech Europe Code manage ethical behavior through specialized rules and sanctions.

Medicinal Products

The most relevant national industry code it the Pharmig Code of Conduct (including ordinances on specific compliance matters) that also sets out obligations that are not required under drug laws.

Key Regulations:

- Transparency rules: member companies must disclose transfers of value (e.g. to HCPs and healthcare organisations) on a regular basis, following PHARMIG's transparency framework. Publication on the PHARMIG website or member companies' websites
- Rules on medical events and hospitality (catering, travel costs)
- Rules on interaction with HCPs, HCOs and patient organizations
- Prohibition of inappropriate gifts and financial incentives
- Regulations on samples and product demonstrations
- Digital and social media guidance.

Sanctions:

- Fines from EUR 5.000 up to 100.000 per violation (€200,000 in case of repeated violations)
- Publication of violations
- In case of repeated violations: increased penalties or exclusion from the association

Medical Devices

The most relevant national industry code it the AUSTROMED Code of Conduct which reflects the EU MedTech Europe Code and focuses on "fair competition" and ethical collaboration.

Key Regulations:

- Sets out several compliance principles and ethical standards in collaboration with healthcare professionals (transparency, separation, arm's length, documentation, external perception of industry members)
- Rules for interaction with healthcare sector, especially R&D and distribution
- Rules on donations, gifts and hospitality
- Rules on events and agreements with HCPs (consultation, know-how, licensing)

Sanctions:

- Association-based measures (warnings, publication of violations)
- In case of serious violations: possible exclusion from the association

Food Supplements:

Food supplements are not covered by a comprehensive industry code, but they follow established ethical and technical guidelines such as IGEPHA: The Austrian Self-Medication Industry association has voluntary guidelines for responsible advertising. Compliance standards are further ensured via competition law enforcement, consumer protection bodies and administrative authorities.

23. Please state 3-5 key decisions by courts or regulatory authorities that have been issued recently and that are relevant for the life sciences sector.

Austria has a traditional civil-law system of codified laws. Especially in a highly regulated industry such as life sciences, the primary focus lies on statutory law (no precedent driven stare decisis system). Still, court decisions, especially of supreme courts, if published, play a strong supplementary role and have persuasive authority especially on agencies/authorities such as BASG/AGES or the social security funds. In exceptional cases the supreme courts can even strike down or reshape statutory rules. The following only provides a cursory glance with focus on (mostly) national decisions:

• **VwGH Ro 2023/10/0366 (11.04.2024):** ruled on classification of products as presentation medicines (Präsentationsarzneimittel) under AMG §1(1) Z1 vs. foods for special medical purposes; AMG rules take precedence, BASG has exclusive jurisdiction.

• **OGH 4 Ob 178/24s (25.02.2025):** confirming earlier interim ruling 4 Ob 80/22a): advertising prohibition in AMG applies only to finished medicinal products, not to active pharmaceutical ingredients (APIs). Advertising of APIs to healthcare professionals is permitted, even if the APIs are marketed as suitable for magistral (pharmacy-compounded) preparations. Decision has influenced promotional strategies for APIs and hospital/specialty compounding.

• **CJEU C-47/22 (Apotheke B. v. BASG, 21.09.2023)** The Court ruled that a holder of a wholesale distribution authorisation (WDA) may only procure medicinal products from persons who themselves hold a WDA (or are exempt). Pharmacies without a WDA do not qualify as supplier, even if authorised to supply the public. Directly affects parallel trade, hospital supply, and pharmacy wholesaling of medicinal products.

• **BASG Enforcement on "Non-Compliant" IVDs (2026):** BASG issued a series of notices regarding IVDs lacking a proper CE mark under the IVDR. BASG has signalled zero tolerance approach for digital or physical diagnostics that have not transitioned to the new EU regulatory framework, resulting in immediate market withdrawals.

• **OGH 4Ob169/24t (17.12.2024):** Upheld market exclusivity for originator drug. In a dispute concerning exclusive distribution rights for a medicinal product in Austria, the Supreme Court upheld the position of the authorised distributor against parallel importers/competitors. Decision is important for market exclusivity, pricing, and supply security of originator and specialty medicines.

• **VfGH G 52/2024 (06.10.2025):** Struck down unconditional ban on non-medically indicated egg retrieval/storage (elective, non-medically indicated oocyte cryopreservation) as disproportionate and unconstitutional, enabling access for reproductive tech.

Landmark decision for assisted reproduction and fertility preservation in Austria.

• **VfGH G 105/2025 (18.12.2025):** Rejected challenge by wholesalers (PHAGO et al.) against Arzneimittel storage and monitoring duties 2026 (MSVAG); no violation of trade freedom or data protection.

• **OGH 4 Ob 19/24h (22.10.2024):** Confirmed liability for defective cough syrup and sleep apnea ventilator; focus on construction/production defects, future damages possible even without current harm.

24. What, if any, are the key legal and regulatory trends in your jurisdiction with regards to the digitalization of the local healthcare system and with regards to the use of artificial intelligence in the life sciences sector? Please briefly describe.

Under national eHealth Strategy Austria 2024–2030 Austria is actively digitalizing its healthcare system through ELGA expansion, DiGA style apps and telemedicine adoption, while preparing for EU AI Act implementation, European Health Data Space and cybersecurity under NIS 2 rules. The strategy is characterized by "Digital before Outpatient before Inpatient," moving toward a fully integrated, data-driven ecosystem.

Digitalization of the Healthcare System

- "App on Prescription" (DiGA) Launch: HCPs will be able to prescribe medical apps with direct reimbursement from social insurance with a focus on ELGA integration. This will also apply to digital therapeutics (DTx)
- Expansion of ELGA (Austrian Electronic Health Record): ELGA will, next to medical document repository, expand its functions (e-medication, e-vaccination record, e-medical findings), strengthen patient rights and complaint mechanisms. Patients can access (or opt out of) their ELGA data via ELGA-Portal and mobile apps.
- Telehealth Integration: Remote consultations and tele-diagnostics are being regulated more clearly regarding reimbursement, video consultations and cross border telemedicine.

Artificial Intelligence 2026

- As of August 2026, the key transparency and governance rules of the EU AI Act are fully applicable in Austria whereby RTR (Regulatory Authority for Broadcasting and Telecommunications) and BASG (for medical-specific AI) will be the competent surveillance bodies to ensure AI safety. Penalties can result in fines up to 35 million EUR or 7% of a company's annual turnover.
- High-Risk Classification: Most AI used in medical devices (e.g., diagnostic software, robotic surgery assistants) is classified as High-Risk (diagnostic/therapeutic decision support, medical imaging analysis, patient triage). Manufacturers must comply with strict requirements for data quality, human oversight, and technical documentation. Thus, AI systems used for clinical decision support, diagnostics, triage or disease management are likely classified as high-risk, requiring: rigorous risk management and governance systems, documentation and transparency obligations, human oversight and reliability measures.
- AI used in medical software or devices (Software-as-Medical-Device or SaMD) continues to be regulated under the EU Medical Device Regulation (MDR). AI functions do not create a separate national regime but must comply with both MDR and, where applicable, AI Act obligations in parallel.
- Software and AI systems will be explicitly defined as "products" under product liability laws making manufacturers, importers and , in certein cases, suppliers strictly liable for defects.

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