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Pharma Legal

Handbook

IRAQ
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Content

About Guide

This guide is essential for navigating the complex regulatory landscape of Iraq's pharma market from market and legal perspectives. Whether you're involved in drug manufacturing, distribution, or compliance, this handbook provides valuable insights to help you stay complied with the requirements of Iraqi laws and competitive to other providers.

The Pharma Legal Handbook: Iraq should answer any questions linked to regulation, pricing, clinical and preclinical trials, marketing, manufacturing, trademarks and patents, cannabinoid medicines, medical cannabis, opioid drugs, orphan drugs and rare diseases, localisation, biologics, and biosimilars.

This guide is designed to help industry players navigate the complex legal landscape in Iraq with confidence and clarity.

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Foreword

This handbook on Pharmaceutical Regulation and Market Access in Iraq is a comprehensive introduction that highlights the key legal and regulatory aspects shaping the pharmaceutical and healthcare sector. It has been prepared by Etihad Law Firm, in collaboration with specialized legal advisors, to serve as a reference for companies, investors, and professionals seeking to navigate Iraq’s evolving pharmaceutical landscape.

Iraq is experiencing a significant transition period with a growing economy, diverse public and private sector projects, and reforms aimed at enhancing the investment environment and attracting international capitals. Our firm is committed to providing comprehensive support to the investors interested in taking advantage of Iraq's sovereign guarantee system.

We hope this guide will serve as a valuable resource, providing clear insights into the mechanisms of sovereign guarantees in Iraq and supporting investors in building and growing their businesses in this promising and opportunistic market.

Ahmed Hankawi
Managing Partner

Executive Summary

Iraq's pharmaceutical and medical-device market is defined by a centralized regulatory gatekeeper, evolving industrial policy, and a mixed public–private demand model. The Ministry of Health "**MOH**" through the Iraq Drug Regulatory Authority "**IDRA**" controls marketing authorization, pricing oversight, pharmacovigilance, inspections, import permissions, and promotion rules. Quality and standards interact with Central Organization for Standardization and Quality Control "**COSQC"** (under the Ministry of Planning), while localization incentives are influenced by the Ministry of Industry & Minerals.

Regulatory essentials.

All medicines (including biologics/biosimilars), medical devices, and most OTC products require IDRA approval based on safety, efficacy, and quality with evidence of GMP (and GCP for trials where applicable). Marketing authorizations are typically time-limited (commonly 5 years) and renewable with updated data. Generics follow an abbreviated, bioequivalence-driven route; biologics and biosimilars require comparability packages. Promotion is tightly controlled (no DTC for medicines), with strict rules on HCP interactions. Cannabis-based products are not authorized; opioids are authorized for medical use under strict controls.

Pricing, reimbursement, and access

Pricing is supervised by MoH/IDRA to balance access and affordability. Reimbursement is predominantly public, supplemented by private insurance in the private sector. Public procurement and tendering are pivotal for volume; distribution runs through licensed importers, wholesalers, hospitals, and pharmacies subject to GDP requirements.

Liability and IP

Product, tort, contract, and in some contexts strict liability apply. Claims can extend to individuals where direct involvement or negligence exists. Patents/trademarks are available subject to standard criteria; there is no dedicated orphan-drug pathway and no bespoke biosimilar statute (general rules apply).

Localization & industrial policy

While authorization remains science-based, broader industrial policy encourages local manufacturing and employment via tariffs, tax incentives, and potential preferences in tenders provided MoH quality requirements are met. Companies should evaluate whether local fill-finish, packaging, or technology transfer can improve pricing and tender competitiveness.

Market dynamics

Demand is driven by population growth, chronic disease burden, and rebuilding of health infrastructure. The public system anchors baseline access; private providers expand choice in urban areas. Supply chains are import-reliant but increasingly open to local production. Key frictions include regulatory variability in practice, tender predictability, customs/logistics, and FX/cash-flow management.

Risk & compliance posture

Expect routine inspections, PV reporting obligations, and strict controls on controlled substances, inducements, and advertising. Penalties range from fines and recalls to license suspension/revocation. Robust SOPs for GMP/GDP, PV, promotion, and distributor oversight are essential.

Exhibits A

PHARMACEUTICAL

01 Regulatory, Pricing, and Reimbursement Overview

What are the regulatory authorities with jurisdiction over drugs, biologicals, and medical devices in your country?	The regulatory authority responsible for drugs, biologicals, and medical devices in Iraq is the Ministry of Health "MoH". There is a dedicated body in MOH known as Iraq Drug Regulatory Authority "IDRA", which oversees the regulations, approvals, and monitoring of these products.
What is the regulatory framework for the authorization, pricing, and reimbursement of drugs, biologicals, and medical devices?	The regulatory framework for the authorization of drugs, biologicals, and medical devices in Iraq involves obtaining approval from IDRA. This process typically includes submitting detailed information on the product's safety, efficacy, and quality. Pricing of drugs is regulated by IDRA and other related departments who setting the guidelines. Reimbursement policies are generally managed by the public healthcare system along with some input from private insurance companies.
What are the steps to obtain authorization to develop, test, and market a product?	To obtain authorization to develop, test, and market a product in Iraq, companies must: • Submit a detailed application to IDRA including the data of the product safety, efficacy, and manufacturing processes. • Provide evidence of compliance with Good Manufacturing Practices "GMPs" and other quality standards. • Obtain approval for clinical trials if required, demonstrate proper testing and validation. • Obtain marketing authorization after review and approval by IDRA.
What are the approximate fees for each authorization?	The fees for authorization depend on the type of the product, its complexity, and the required evaluation processes. Exact fee structures are set by IDRA which are vary. You would need to consult IDRA or related departments of MoH regarding the fees' details
For how long are marketing authorizations/registrations valid? How are marketing authorizations/registrations renewed?	Marketing authorizations in Iraq are typically valid for a set period often 5 years. To renew, companies must submit a renewal application to IDRA providing updated data on safety, efficacy, and quality. The renewal process may require additional testing or data need to be submitted.
How does the authorization process differ between brand-name products and generic products? Are there differences for local manufacturers versus foreign-owned manufacturers?	Brand-name products usually require more extensive data and clinical trials for approval. Generic products often subject to an abbreviated approval process, focusing on demonstrating bioequivalence to an existing approved product. Local manufacturers may have different compliance requirements than foreign-owned manufacturers, but both must meet IDRA standards.

How are combination products (drug - drug, drug - biologic, drug - device, biologic - device, drug - biologic - device) regulated?	Combination products in Iraq are regulated by IDRA. Companies must submit detailed information for the combined components' safety and efficacy. The review process may require additional documentation or testing to ensure compatibility and safety.
How is compliance with regulation monitored and evaluated? Is the regulatory regime comparable with the U.S. Food and Drug Administration or the European Medicines Agency expectations an requirements?	Compliance is monitored by a regular inspection, audits, and reporting requirements. The regulatory regime in Iraq is designed to align with international standards, but there may be variations compared to U.S. Food and Drug Administration “FDA” or European Medicines Agency “EMA” expectations. Compliance with GMPs and Good Clinical Practices “GCPs” is emphasized.
What is the potential range of penalties for noncompliance?	Penalties for noncompliance in Iraq can range from fines and product recalls to suspension or revocation of marketing authorizations. In severe cases, legal action may be taken. The exact penalties depend on the severity of the noncompliance and the violated regulations.
Is there a national healthcare system? If so, how is it administered and funded?	Iraq has a national healthcare system administered by MoH. It is primarily funded by the government’s budgets and provides healthcare services to the public. However, the system has faced challenges in recent years, leading to a mix of public and private healthcare services.
How does the government (or public) healthcare system function with private sector healthcare?	The public healthcare system provides essential services, while the private sector offers additional healthcare options. The private sector plays a significant role in supplementing public services, especially in areas where the public resources are limited.
Are prices of drugs and devices regulated and, if so, how?	Drug and device prices are regulated in Iraq by MoH and IDRA who are setting the guidelines. These guidelines are intended to ensure affordability and accessibility of healthcare products.
How are drugs and devices used by patients paid for? What roles do public and private payers play?	Payment for drugs and devices is primarily by the public healthcare system. Private insurance companies may also play a role, particularly in the private healthcare sector.
Who dispenses drugs and devices to patients and how are those dispensers compensated?	Drugs and devices are dispensed by licensed pharmacists and medical professionals. Compensation depends on the specific role and context, with pharmacists typically compensated through salaries or fees for service.
What are the professional and legal responsibilities of those who dispense drugs and devices? What role do they play in providing patient care, information, and safety?	Professionals who dispense drugs and devices must comply with IDRA regulations and adhere to the ethical standards. They are responsible for ensuring patient’s safety, providing accurate information, and reporting adverse events or safety concerns.

02 Preclinical & Clinical Trial Requirements

Are clinical trials required to be conducted locally as a condition (stated or implicit) for marketing approval?	In Iraq, it is not always explicitly required that the clinical trials be conducted locally for marketing approval. However, if local data are requested, companies must comply with these requirements. Local clinical trials might be required to understand how a product performs in the specific context of the Iraqi population, given its unique demographics and health profile.
How are clinical trials funded?	Clinical trials in Iraq are typically funded by the sponsoring company, which could be a pharmaceutical or biotech company, or a research institution. Funding could also come from academic grants, government programs, or partnerships with international organizations. Funding generally covers all the aspects of the clinical trial, including research, patient compensation, facility costs, and data analysis.
What are the requirements for preclinical and clinical trial protocols? Who must approve the protocols?	Preclinical and clinical trial protocols in Iraq must meet specifically ethical and scientific standards. These protocols typically include detailed plans to conduct the trial, including the study design, patient selection criteria, safety measures, and data analysis methods. The protocols must be approved by an Ethics Committee and often require review by IDRA or MoH before the trial can begin.
What are the requirements for consent by participants in clinical trials?	Consent from participants in clinical trials in Iraq must be informed and voluntary. The informed consent process involves providing participants with a clear information about the trial's purpose, procedures, risks, benefits, and the right to withdrawal at any time. Consent must be documented, typically in writing, and must meet the ethical standards set out by the local ethics committee or other regulatory bodies.
May participants in clinical trials be compensated?	Participants in clinical trials in Iraq may be compensated, but this compensation should not be so high as to unduly influence or coerce participation. Compensation can cover expenses such as travel, time off work, and inconvenience caused by the trial, but it must be reasonable and in consistent with the ethical guidelines.
How are participants in clinical trials protected and indemnified against any harm that arises as a result of participation in the trial?	Participants in clinical trials in Iraq are protected by a combination of the informed consent, ethical oversight, and regulatory compliance. Sponsors of clinical trials are typically required to have insurance or indemnification provisions to cover any harm or adverse events that participants may experience during the trial. Additionally, the ethics committee reviews safety protocols to ensure participants' well-being, and there are mechanisms for reporting and addressing the adverse events.

03 Marketing, Manufacturing, Packaging & Labeling, Advertising

What is the authorization process for the marketing of new drugs, biologics, medical devices, over- the-counter medications, and other medicinal products?	In Iraq, the authorization process for marketing new drugs, biologics, medical devices, over-the-counter “OTC” medications, and other medicinal products is managed by IDRA at MoH. Companies must submit an application that includes detailed information on the product's safety, efficacy, quality, manufacturing processes, and clinical data, where applicable. Upon submission, IDRA reviews the data and determines if the product is suitable for the Iraqi market. Once approved, a marketing authorization is granted.
What is the authorization process for the marketing of generic versions of these products?	The process for the generic products in Iraq generally involves demonstrating bioequivalence to a reference product. The application for marketing authorization of a generic product requires providing data on the formulation, manufacturing processes, and clinical studies or trials demonstrating that the generic product meets the same standards as the brand-name counterpart. IDRA reviews these submissions before granting approval.
What are the typical fees for marketing approval?	Fees for marketing approval in Iraq depend on the type of product and its complexity. The fees cover the cost of reviewing and evaluating the application. The exact fee structure is determined by IDRA or MoH, and applicants should consult these bodies for current fee schedules.
What is the period of authorization and the renewal process?	Marketing authorizations in Iraq are typically valid for a set period, often (5) years. The renewal process requires companies to submit the updated information, including safety, efficacy, and quality data. Renewals must be approved by IDRA and may be required for additional evaluations.
What are the requirements, if any, for post-approval pharmacovigilance?	Post-approval pharmacovigilance is essential in Iraq. Companies must monitor their products after approval, reporting any adverse events or safety concerns to IDRA. This includes maintaining systems for adverse event detection, investigation, and reporting, as well as periodic safety updates.
Are foreign marketing authorizations recognized?	In Iraq, foreign marketing authorizations are recognized to some extent, especially from reputable agencies like the U.S. FDA or EMA. However, products still need to meet local requirements and obtain approval from IDRA before marketed in Iraq.
Are parallel imports of medicines or devices allowed?	Parallel imports are generally allowed in Iraq but subject to the strict regulations. IDRA sets guidelines to ensure that imported products meet local safety and quality standards. This includes verifying the product's origin, documentation, and compliance with local regulations.

What are the restrictions on marketing practices such as gifts, sponsorships, consultancy agreements, travel and entertainment, or other incentives for healthcare organizations and individual medical practitioners?	Marketing practices in Iraq subject to restrictions to prevent conflicts of interest and undue influence on healthcare decisions. Gifts, sponsorships, consultancy agreements, travel, and entertainment are regulated to ensure the ethical practices. Companies must follow the ethical guidelines, and IDRA or MoH provide specific rules regarding these practices.
How is the manufacturing of medicines and devices regulated and by which agencies?	Manufacturing of medicines and devices in Iraq is regulated by IDRA and MoH. Companies must comply with Good Manufacturing Practices "GMPs", and IDRA oversees inspections and compliance. Manufacturing facilities must meet stringent quality standards to ensure product safety.
Are local manufacturing requirements compatible with Good Manufacturing Practices (GMPs) as defined by the U.S. Food & Drug Administration and/or the European Medicines Agency?	Local manufacturing in Iraq must comply with GMPs, which are designed to align with the international standards, including those of FDA and EMA. Compliance with GMPs is essential for ensuring product safety and quality.
What is the inspection regime for manufacturing facilities?	Manufacturing facilities in Iraq subject to regular inspections by IDRA or MoH to ensure compliance with GMPs and other regulatory requirements. Inspections can occur on a scheduled basis or as a result of specific concerns or complaints.
Are manufacturing facilities open for inspection by foreign inspectors or third-party inspectors as authorized by the FDA/EMA?	Manufacturing facilities in Iraq are generally open for inspection by foreign inspectors or third-party inspectors authorized by the international agencies like FDA or EMA. These inspections ensure compliance with the global quality standards.
What are the requirements for storage, packaging, and handling of medicines and devices and their constituent components?	Storage, packaging, handling of medicines and devices in Iraq must comply with the specific regulations to ensure product integrity and safety. Requirements include the appropriate temperature control, secure storage, and proper labeling. These regulations aim to prevent contamination and ensure the product quality.
What information must be included in medicine and device labeling?	Medicine and device labeling in Iraq must include key information such as the product name, active ingredients, dosage instructions, warnings, manufacturer details, and expiration dates. These information ensures that healthcare professionals and consumers have the necessary information to use the product safely.
What additional information may be included in labeling and packaging?	Additional information can be included in labeling and packaging may consist of usage instructions, storage recommendations, and relevant safety information. However, these additional information must not be misleading or contradict the regulatory requirements.

What items may not be included in labeling and packaging?	Items not allowed in labeling and packaging include misleading information, unverified claims, and any content that could result in inappropriate or unsafe use of the product. Regulatory authorities closely monitor labeling and packaging to ensure the compliance.
What are the restrictions and requirements for the marketing and advertising of medicines and devices?	Marketing and advertising of medicines and devices in Iraq are subjected to strict rules to ensure the ethical practices. Misleading advertisements, false claims, or unapproved endorsements are prohibited. Companies must follow IDRA guidelines when marketing products to healthcare professionals or the public.
Where can medicines and devices be sold or delivered? Can medicines and devices be sold or delivered via post?	Medicines and devices in Iraq can be sold through adopted authorized licensed pharmacies, hospitals. Delivery via post is generally permitted but must comply with regulatory guidelines to ensure product safety during transit.
What are the restrictions and requirements for electronic marketing and advertising via email, by Internet, social media, and other channels?	Electronic marketing and advertising in Iraq are also regulated. Companies must ensure that online advertisements, social media posts, and email campaigns comply with the regulatory guidelines, avoiding misleading claims and respecting consumer privacy.
May medicines and devices be advertised or sold directly to consumers?	Direct advertising or sale of devices to consumers is generally allowed in Iraq but must adhere to strict regulatory guidelines. Companies must ensure that advertising is accurate, not misleading, and does not promote inappropriate use of the product. It’s not allowed to advertise the medicines.
How is compliance monitored?	Compliance in Iraq is monitored by a regular inspection, audit, and reports submitted to IDRA. Regulatory authorities ensure that companies comply with the regulations to maintain product safety and quality.
What are the potential penalties for noncompliance?	Penalties for noncompliance in Iraq vary depending on the severity and nature of the violation. Penalties maybe fines, product recalls, suspension or revocation of marketing authorizations, and legal action. IDRA determines penalties based on the specific circumstances of noncompliance.

04 Traditional Medicines & Over Counter Products

What are the regulatory requirements for traditional, herbal, complementary, or alternative medicines and devices?	Traditional, herbal, complementary, or alternative medicines and devices in Iraq are subjected to the regulations of IDRA under MoH. Manufacturers or importers of these products must ensure it meets safety and quality standards. Typically, this requires submitting the relevant documentation, such as safety data, manufacturing processes, and evidence of traditional use or scientific support to obtain approval.
Can these traditional, herbal, complementary, or alternative products be advertised directly to the public?	In Iraq, advertising traditional, herbal, complementary, or alternative products directly to the public is generally permitted, but it is subjected to the regulatory oversight. Advertisements must not make false or misleading claims, and products must be approved by IDRA before advertising.
What health, advertising, and marketing claims may be made for traditional, herbal, complementary, or alternative products?	Claims made for traditional, herbal, complementary, or alternative products must be accurate and supported by evidence. They cannot claim to cure, prevent, or treat serious diseases unless there's substantial scientific proof. IDRA reviews marketing claims to ensure it aligns with these requirements.
What are the regulatory requirements for over-the-counter (non-prescription) medications?	OTC medications in Iraq are regulated by IDRA. The regulatory requirements include demonstrating safety, efficacy, and quality. Manufacturers must submit detailed information about the product's composition, manufacturing process, and intended use to obtain approval for OTC sales.
Are there any limitations on locations or channels through which OTC products may be sold?	In Iraq, OTC products are generally sold through adopted authorized licensed pharmacies, drugstores. There are limitations to ensure that these products are dispensed appropriately and that customers have access to knowledgeable professionals for advice.
What health, advertising, and marketing claims may be made for OTC products?	OTC products can be advertised, but health claims must be accurate and not misleading. IDRA oversees advertising and marketing to ensure compliance with these regulations. Companies must avoid making exaggerated claims or promoting inappropriate use.
Can OTC products be marketed or advertised directly to the public?	Yes, OTC products can be marketed or advertised directly to the public in Iraq, but advertisements must follow the regulatory guidelines. Companies should ensure that the advertisements do not mislead consumers or promote inappropriate or unsafe use of the product.

What is the mechanism by which a prescription-only product can be converted to an OTC product?	Converting a prescription-only product to an OTC product in Iraq requires approval from IDRA. The process typically involves demonstrating that the product is safe for self-administration without a prescription with clear instructions for use and warnings. Manufacturers must submit data supporting this conversion and IDRA evaluates whether it is appropriate or not.
What are the requirements for the importation of either traditional medicines or OTC products?	The importation of the traditional medicines or OTC products in Iraq requires compliance with IDRA regulations. Importers must obtain permits or licenses, and must ensure that imported products meet safety and quality standards. Documentation such as Certificates of Analysis, origin information and other regulatory paperwork is typically required.

05 Product Liability

What types of liability are recognized in your jurisdiction?	Iraq recognizes several types of liability, including: ▪ Product Liability: Relating to harm caused by defective products. ▪ Tort Liability: Involving personal injury or property damage due to negligence or other wrongful acts. ▪ Contractual Liability: Stemming from breach of contract or warranty. ▪ Strict Liability: Where liability exists regardless of fault or intent, often in cases involving inherently dangerous activities or products.
How do these types of liabilities apply to the manufacturers of medicines and devices?	Manufacturers of medicines and devices in Iraq are subjected to product liability and other related liabilities. They must ensure that their products are safe, effective, and meet regulatory standards. If a product is defective and causes harm, the manufacturer can be held liable for damages. Liability can arise from defects in manufacturing, design, or failure to provide adequate warnings or instructions.
Does potential liability extend to the manufacturer only or could claims extend to corporate executives, employees, and representatives?	In Iraq, liability can extend beyond the manufacturer to corporate executives, employees, and representatives. While the primary liability often falls on the manufacturing company, individual employees or executives could be held personally liable if they were directly involved in the actions leading to harm or if their negligence or misconduct contributed to the defect or injury.
How can a liability claim be brought?	A liability claim in Iraq can be brought through: ▪ Civil Litigation: A lawsuit filed by the injured party seeking compensation for damages. ▪ Consumer Protection Agencies: Some cases may involve regulatory bodies focused on consumer rights. ▪ Arbitration or Mediation: In certain cases, disputes might be resolved through alternative dispute resolution mechanisms. A claim typically requires demonstrating that a defect or negligence caused harm and that the manufacturer or other parties are responsible for the defect.

What defenses are available?	Defenses against liability claims in Iraq may include: ▪ Absence of Defect: Proving that the product was not defective or met all safety standards. ▪ Contributory Negligence: Arguing that the injured party's own negligence contributed to the harm. ▪ Assumption of Risk: If the injured party knew the risks and voluntarily accepted them. ▪ Statute of Limitations: If the claim is brought after the legally allowed time frame. ▪ Compliance with Regulations: Demonstrating that the product adhered to all relevant regulations and standards. ▪ Misuse of Product: If the harm resulted from the user's misuse of the product contrary to instructions or common practice. These defenses can vary depending on the case's details, involved product, and the extent of harm caused. Legal counsel is typically required to navigate these defenses effectively.

06 Patents and Trademarks

What are the basic requirements to obtain patent and trademark protection?	Patent: To obtain a patent, the invention must be new (novel), involve an inventive step (non-obvious), and be capable of industrial application. In Iraq, the invention must be disclosed in a clear and complete manner.	Trademark: To obtain trademark protection, a trademark must be distinctive and not likely to cause confusion with the existing trademarks. The trademark must not describe the goods or services it represents, and it cannot be immoral or against public policy.
What agencies or bodies regulate patents and trademarks?	Patents: The regulatory body responsible for patents in Iraq is the Central Organization for Standardization and Quality Control "COSQC", part of the Ministry of Planning.	Trademarks: The Ministry of Industry and Minerals oversees trademark regulation in Iraq.
What products, substances, and processes can be protected by patents or trademarks and what types cannot be protected?	Patents: can protect products, processes, and substances, including pharmaceuticals, medical devices, and industrial processes. However, some subjected matters are not patentable, such as scientific theories, mathematical methods, business methods, and methods for medical treatment.	Trademarks: can protect brand names, logos, symbols, and other trademarks that distinguish goods or services. Items that are generic, misleading, or offensive cannot be trademark.
How can patents and trademarks be revoked?	Patents: can be revoked if granted by mistake, if the invention was not novel, or the patent holder does not comply with the regulatory requirements, or it's not used within the specified timeframe.	Trademarks: can be revoked if it's not used for a certain period or was registered in bad faith, or become generic through common usage.
Are foreign patents and trademarks recognized and under what circumstances?	Foreign patents and trademarks can be recognized in Iraq if the country of origin is part of the international agreements or treaties to which Iraq is a party, such as Paris Convention or TRIPS (Agreement on Trade-Related Aspects of Intellectual Property Rights). This recognition often requires registration with the Iraqi authorities.	
Are there any non-patent/trademark barriers to competition to protect medicines or devices?	Non-patent/trademark barriers may include regulatory approval from the Ministry of Health or other government agencies, certification from COSQC, import restrictions, and government procurement policies. These barriers are often related to the safety, quality in compliance with the national standards.	

Are there restrictions on the types of medicines or devices that can be granted patent and trademark protection?	Restrictions on patent protection may include exclusions for naturally occurring substances, diagnostic methods, surgical techniques, and therapies. For trademarks, restrictions can include trademarks that are generic, descriptive of the product or service, or likely to cause confusion with the existing trademarks.
Must a patent or trademark license agreement with a foreign licensor be approved or accepted by any government or regulatory body?	In Iraq, patent or trademark license agreements with the foreign licensors often require approval or registration with a government or regulatory body. This ensures compliance with local laws, intellectual property rights, and other regulatory requirements. The exact process may involve submitting the licensing agreement to relevant authorities, providing necessary documentation, and complying with the financial or operational requirements.

07 Product Liability

What types of liability are recognized in your jurisdiction?	Iraq recognizes several types of liability, including: ▪ Product Liability: Relating to harm caused by defective products. ▪ Tort Liability: Involving personal injury or property damage due to negligence or other wrongful acts. ▪ Contractual Liability: Stemming from breach of contract or warranty. ▪ Strict Liability: Where liability exists regardless of fault or intent, often in cases involving inherently dangerous activities or products.
How do these types of liabilities apply to the manufacturers of medicines and devices?	Manufacturers of medicines and devices in Iraq are subjected to product liability and other related liabilities. They must ensure that their products are safe, effective, and meet regulatory standards. If a product is defective and causes harm, the manufacturer can be held liable for damages. Liability can arise from defects in manufacturing, design, or failure to provide adequate warnings or instructions.
Does potential liability extend to the manufacturer only or could claims extend to corporate executives, employees, and representatives?	In Iraq, liability can extend beyond the manufacturer to corporate executives, employees, and representatives. While the primary liability often falls on the manufacturing company, individual employees or executives could be held personally liable if they were directly involved in the actions leading to harm or if their negligence or misconduct contributed to the defect or injury.
How can a liability claim be brought?	A liability claim in Iraq can be brought through: ▪ Civil Litigation: A lawsuit filed by the injured party seeking compensation for damages. ▪ Consumer Protection Agencies: Some cases may involve regulatory bodies focused on consumer rights. ▪ Arbitration or Mediation: In certain cases, disputes might be resolved through alternative dispute resolution mechanisms. A claim typically requires demonstrating that a defect or negligence caused harm and that the manufacturer or other parties are responsible for the defect.

Exhibits B

CANNABINOID
OPIOID
MEDICINAL
CANNABIS

08 Cannabinoid Drugs

Are Cannabinoid Drugs authorized in your country?	In Iraq, Cannabinoid Drugs are generally not authorized due to strict drug control laws and cultural sensitivities around cannabis-related substances.
What are the regulatory authorities with jurisdiction over Cannabinoid Drugs?	The Ministry of Health and related drug regulatory bodies oversee drug control and authorization, including laws prohibiting cannabinoid drugs.
Is there a specific regulatory framework for the authorization, pricing, and reimbursement of Cannabinoid Drugs?	Given that Cannabinoid Drugs are not typically authorized, there is no specific framework for their authorization, pricing, or reimbursement
Which are the cannabinoid drugs that have received market approval to date?	There are no known cannabinoid drugs with market approval in Iraq.
Who can prescribe Cannabinoid Drugs?	Since these drugs are generally not authorized, prescribing them is not permitted
Is there a list of doctors authorized to prescribe Cannabinoid Drugs?	No, because Cannabinoid Drugs are not typically authorized for medical use in Iraq.
What approvals or notifications are required to prescribe Cannabinoid Drugs?	This is not applicable, as Cannabinoid Drugs are not authorized
Which organizations are authorized to sell/distribute Cannabinoid Drugs available?	Organizations cannot legally sell or distribute Cannabinoid Drugs in Iraq.
Is there a list of retailers/distributors authorized to sell Cannabinoid Drugs?	There are no retailers in Iraq. Since these drugs are not authorized, there are no adopted distributors
Are there proposals for reform or significant change to the regulation of Cannabinoid Drugs?	There are no significant proposals for changing regulations related to Cannabinoid Drugs in Iraq.
When are they likely to come into force?	This is not applicable due to the lack of authorization or reform proposals for Cannabinoid Drugs in Iraq.

09 Medicinal Cannabis

Is Medicinal Cannabis authorized in the country?	Medicinal Cannabis is not authorized in Iraq. Cannabis-related substances are generally illegal due to strict drug control laws
What are the regulatory authorities with jurisdiction over Medicinal Cannabis?	The Ministry of Health and related regulatory bodies govern all drug-related laws, including those prohibiting cannabis
What is the regulatory framework for the authorization, pricing, and reimbursement of Medicinal Cannabis?	Since Medicinal Cannabis is not authorized, there is no specific framework for its authorization, pricing, or reimbursement
How is the production and import of Medicinal Cannabis regulated and by which agencies/authorities?	Production and import of Medicinal Cannabis are prohibited in Iraq
What approval or notifications are necessary to produce or import Medicinal Cannabis?	This is not applicable due to the prohibition on Medicinal Cannabis production and import
What is the regulatory framework for the marketing and distribution of Medicinal Cannabis?	Since Medicinal Cannabis is not allowed, there is no framework for marketing or distribution
How can patients obtain Medicinal Cannabis?	Patients cannot legally obtain Medicinal Cannabis in Iraq
Who can prescribe Medicinal Cannabis?	Since it is prohibited, no one is authorized to prescribe Medicinal Cannabis
Is there a list of doctors authorized to prescribe Medicinal Cannabis?	There is no such list, as Medicinal Cannabis is not authorized
What approvals or notifications are required to prescribe Medicinal Cannabis?	Approvals and notifications are not applicable because Medicinal Cannabis is not permitted
Where is Medicinal Cannabis available?	Medicinal Cannabis is not legally available in Iraq.
Is there a list of retailers authorized to sell Medicinal Cannabis?	There are no authorized retailers for Medicinal Cannabis in Iraq
Are there proposals for reform or significant change to the regulation of Medicinal Cannabis?	There are no significant proposals for reform regarding Medicinal Cannabis regulation

10 Opioid Drugs

Are Opioid Drugs authorized in your country?	Yes, Opioid Drugs are authorized in Iraq for medical purposes but are tightly regulated
What are the regulatory authorities with jurisdiction over Opioid Drugs?	The Ministry of Health and the relevant drug regulatory bodies oversee the authorization and control of Opioid Drugs
Is there a specific regulatory framework for the authorization, pricing, and reimbursement of Opioid Drugs?	Yes, the regulatory framework for Opioid Drugs is governed by laws and regulations set by the Ministry of Health, which controls their authorization, pricing, and reimbursement.
Which are the Opioid drugs that have received market approval to date?	Specific details on market-approved Opioid Drugs in Iraq can be obtained from the Ministry of Health. These typically include commonly used medical opioids like morphine, codeine, and fentanyl.
Who can prescribe Opioid Drugs?	Opioid Drugs can be prescribed by licensed medical professionals, such as doctors or specialists with the necessary authorization
Is there a list of doctors authorized to prescribe Opioid Drugs?	While there's no public list, doctors authorized to prescribe opioids must meet specific regulatory requirements and hold the necessary licenses
What approvals or notifications are required to prescribe Opioid Drugs?	Prescribing Opioid Drugs requires proper medical licensing and compliance with Ministry of Health guidelines for prescribing controlled substances. Notifications to regulatory bodies might be required in some cases, especially for high-risk opioids or large quantities.
Which organizations are authorized to sell/distribute Opioid Drugs available?	Licensed pharmacies and medical facilities are authorized to sell/distribute Opioid Drugs, subject to strict regulatory control by the Ministry of Health
Is there a list of retailers/distributors authorized to sell Opioid Drugs?	There are no retailers in Iraq. And there is no public list for the distributors, but authorized distributors must meet strict licensing and regulatory requirements.
Are there proposals for reform or significant change to the regulation of Opioid Drugs?	Proposals for reform often focus on strengthening regulations, improving drug monitoring systems, and reducing the risk of opioid misuse and abuse
When are they likely to come into force?	The timeline for regulatory reforms related to Opioid Drugs varies and depends on government initiatives and legislative processes. Significant changes can take years to implement. However, any reform proposals aiming to enhance control over opioid use or improve safety could be influenced by ongoing international efforts to address the opioid crisis and drug misuse.

Exhibits C

Orphan Drugs & Rare Diseases

11 Orphan Drugs & Rare Diseases

What is the definition of Rare Diseases in your country?	In Iraq, there is no specific definition of rare diseases in the legal or regulatory framework. The concept of rare diseases generally refers to conditions affecting a small percentage of the population, but an official definition may be absent or ambiguous.
Does the designation of 'Orphan Drug' exist in your country? (Does it correspond with the definition of Rare Diseases?)	Iraq does not have a formal designation for "orphan drugs." This term is generally used in countries with specific policies to encourage the development and distribution of drugs for rare diseases. Without a distinct definition of rare diseases, the designation of orphan drugs is not clearly established in Iraq.
What is the regulatory framework for the authorization of an Orphan Drug? (Is this regulatory framework based on Rare Disease status or can it alternatively be based on Orphan Drug foreign status?)	Since Iraq does not have a formal designation for orphan drugs, there is no specific regulatory framework for their authorization. Any drug authorization in Iraq follows the general guidelines set by the Ministry of Health and related agencies, with requirements for safety, efficacy, and quality. There is no specific pathway for orphan drugs based on rare disease status or foreign orphan drug designation.
Does your country have provisions for relaxed clinical trial/scientific evidence requirements in respect of Orphan Drugs as compared to other drugs?	Iraq does not have a separate framework for orphan drugs, so there are no specific provisions for relaxed clinical trial or scientific evidence requirements. All drugs must meet the general safety and efficacy requirements for approval.
Is there an expedited pathway for Orphan Drugs?	Without a specific regulatory framework for orphan drugs, there is no expedited pathway for these drugs in Iraq. All drugs undergo the standard approval process with the Ministry of Health.
Are foreign marketing authorizations recognized in your jurisdiction for Orphan Drugs? If yes, marketing authorizations from which countries are recognized?	Iraq does not have a unique process for recognizing foreign marketing authorizations for orphan drugs. However, foreign marketing authorizations for general drugs are often considered from countries with established regulatory bodies like the FDA (United States), EMA (European Union), or similar organizations. Recognition typically requires additional review and approval by the Iraqi Ministry of Health.
Can Orphan Drugs be reimbursed? If so, is there a specific reimbursement procedure for Orphan drugs?	Given the lack of a specific framework for orphan drugs, there is no distinct reimbursement procedure for them in Iraq. Reimbursement for medications is generally determined by public health programs or insurance providers based on the established criteria and budget considerations.

How are the prices of Orphan Drugs regulated?	Pricing for drugs, including orphan drugs, falls under the general regulatory framework in Iraq. Prices are typically regulated by the Ministry of Health, which evaluates factors like production costs, import fees, and market demand to determine appropriate pricing. There is no distinct regulation specific to orphan drugs.
In case of reference price based on a basket of countries, what countries are included?	Iraq does not typically use a reference pricing system based on a basket of countries for orphan drugs, as there is no specific framework for these drugs. For general drug pricing, Iraq might consider prices from other countries, especially in the Middle East, but the exact basket of countries used for reference pricing is not clearly defined.
Have there been any significant legal/judicial developments in relation to Orphan Drugs in your country?	There are no significant legal or judicial developments related to orphan drugs in Iraq due to the absence of a specific framework for these drugs. Developments generally pertain to broader pharmaceutical regulations and drug safety.
Are there proposals for reform or significant change to the regulation of Orphan Drugs? If yes, when are they likely to come into force?	Given the lack of a distinct orphan drug framework in Iraq, there are no significant proposals for reform or change in regulation. Changes to drug regulation in Iraq tend to focus on broader issues like drug safety, quality, and general pharmaceutical governance. If there were to be proposals for orphan drug reform, they would likely be tied to broader efforts to improve healthcare infrastructure and drug regulation. The timeline for such changes would depend on political developments, regulatory priorities, and the capacity for reform in the healthcare sector.

Exhibits D

Localization

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Are there any rules or regulations requiring and/or encouraging localization in your country? What is the legal framework defining these localization rules and policies?	Localization policies in Iraq generally aim to encourage local production, increase employment, and reduce dependence on imported goods. These rules and regulations may not be specific to the pharmaceutical industry but instead relate to broader industrial policies. The Ministry of Industry and Minerals is a key regulatory body involved in promoting localization and supporting domestic industries. The legal framework includes various laws and regulations that incentivize local production and industry development.
Have there been any recent significant changes involving localization rules? If yes, when did they take place and what did they involve?	Iraq has undergone significant changes in its economic and industrial policies, primarily aimed at revitalizing local industries after years of conflict and instability. Recent changes in localization rules may include incentives for foreign investment, tax benefits for local manufacturing, and support for rebuilding domestic industries. However, specifics related to the pharmaceutical sector might be less defined, focusing more on broader industrial development.
Is the process of obtaining a marketing authorization impacted by localization policies in your country? If yes, how so (what are the incentives received or the requirements)?	Localization policies do not typically impact the process of obtaining marketing authorization for pharmaceutical products in Iraq. Marketing authorization is primarily governed by the Ministry of Health, focusing on safety, efficacy, and compliance with health regulations. However, local manufacturers may have streamlined processes or incentives to promote domestic production.
Is the pricing process for pharmaceutical products impacted by localization policies in your country? If yes, how so (what are the incentives received or the requirements)?	Localization policies in Iraq do not specifically impact the pricing process for pharmaceutical products. Pricing is primarily governed by the Ministry of Health and is influenced by factors like production costs, import tariffs, and market dynamics. Local manufacturers may have some advantages in terms of lower transportation costs and reduced import fees, indirectly impacting pricing.
Is the reimbursement of pharmaceutical products impacted by localization policies in your country? If yes, how so (what are the incentives received or the requirements)?	Reimbursement of pharmaceutical products in Iraq is typically determined by public health programs or insurance providers. Localization policies do not generally impact reimbursement directly, as these policies focus on broader industrial development rather than specific healthcare financing.
Is the access to public or public tenders of pharmaceutical products impacted by localization policies in your country? If yes, how so (what are the incentives received or the requirements)?	Localization policies may impact access to public tenders for pharmaceutical products in Iraq, as the government may prefer to source from local manufacturers to support domestic industries. Public procurement policies may offer incentives or set quotas for locally produced products. However, these policies must align with quality and safety requirements set by the Ministry of Health.

Are import tariffs, importation and/or exportation permits, trade and/or taxation of pharmaceutical products impacted by localization policies in your country? If yes, how so?	Localization policies in Iraq may influence import tariffs, importation/exportation permits, and trade/taxation of pharmaceutical products. The government might impose higher tariffs on imported products to encourage local manufacturing or provide tax incentives to local producers. Importation and exportation permits are typically managed by the Ministry of Health and customs authorities, with an aim to balance import needs with domestic industry support.
Are there any other incentives or advantages offered by the current local localization rules in your country? If yes, what are they?	Incentives under localization policies may include tax breaks, reduced import tariffs for raw materials used in local production, and government support for domestic industries through subsidies or public contracts. The focus is on encouraging local manufacturing and investment in the Iraqi economy.
Are there discussions about the possibility of implementing localization policies in your country? If yes, what are the proposed reforms and when should they come into place?	Discussions about implementing or expanding localization policies in Iraq are ongoing, with a focus on economic diversification and reducing reliance on imports. Proposed reforms may include additional incentives for local manufacturing, increased government support for domestic industries, and changes to import/export regulations to promote localization. The timeline for these reforms varies, depending on political stability, economic priorities, and legislative processes.

Exhibits E

Biosimilars & Biologics

12 Biosimilars & Biologics

Are biosimilar medicines considered the same as generic medicines in your country?	No, biosimilar medicines are not considered the same as generic medicines in Iraq. Generic medicines are chemically identical to their branded counterparts, while biosimilars are derived from living organisms and are similar but not identical to the original biologic product.
Are all biologic medicines, including biosimilar medicines patentable in your country?	Yes, all biologic medicines, including biosimilars, are patentable in Iraq, provided they meet the criteria for patentability, such as novelty, inventiveness, and industrial applicability.
Is there a specific regulatory framework for the marketing authorization of biosimilar medicines in your country? If yes, what is the regulatory framework for the authorization of biosimilar medicines?	No specific regulatory framework is dedicated solely to biosimilar medicines in Iraq. The general framework for pharmaceutical products applies, governed by the Ministry of Health. Approval requirements for biosimilars typically include safety and efficacy data, similar to biologic medicines.
What kind of data package is needed to obtain approval for a biosimilar drug? Is this any different to the requirements for the original Biologics drug?	Biosimilar medicines require a comprehensive data package demonstrating that the product is highly similar to the original biologic drug. This includes analytical, nonclinical, and clinical data. While the data package for biosimilars is designed to prove similarity, the requirements for original biologics focus on demonstrating safety and efficacy from scratch.
What are the requirements for the choice of the reference comparator product?	The reference comparator product for biosimilars must be an approved biologic medicine with established safety and efficacy profiles. In Iraq, the chosen comparator product should ideally be one approved by reputable international regulatory agencies like the FDA or EMA.
Can the comparator product be sourced from another regulatory jurisdiction? If yes, what are the data needed to support this approach?	Yes, the comparator product can be sourced from another regulatory jurisdiction, typically from countries with established pharmaceutical regulatory frameworks. The data required to support this approach include evidence of approval from the foreign jurisdiction and proof that the comparator product meets Iraqi regulatory standards.

What is the reimbursement policy for biosimilar medicine? Is this any different to the requirements for the original Biologics drug?	Reimbursement policy for biosimilars in Iraq generally aligns with the broader policy for pharmaceuticals. Reimbursement depends on public health programs, insurance providers, and specific agreements with healthcare facilities. There might be differences in reimbursement rates due to the potential cost savings offered by biosimilars compared to original biologics.
Does biosimilar competition impact the reimbursement policy of the originator reference products?	Biosimilar competition can impact the reimbursement policy for originator products by driving down costs, leading to reduced reimbursement rates for the original biologics. However, this impact might not be as pronounced in Iraq due to the relatively new market for biosimilars and limited regulatory frameworks focusing on cost-based competition.
What is the legal framework for biosimilar medicines prescribing (clinical decision maker) and dispensing (pharmacy level, hospital or retail)? Is this any different to the requirements for the original Biologics drug?	The legal framework for prescribing and dispensing biosimilar medicines in Iraq follows the general pharmaceutical guidelines set by the Ministry of Health. The requirements are not notably different from those for original biologics, focusing on proper licensing, safety, and compliance.
Is the system considering physician-led switching and/or pharmacy-level substitution (without involvement of the clinical decision maker)?	Physician-led switching may be considered when prescribing biosimilars, but pharmacy-level substitution without the involvement of a clinical decision-maker is less likely due to the complex nature of biologics and biosimilars. The system in Iraq generally requires a physician's approval for changes in treatment.
What are the post - authorisation requirements (including pharmacovigilance, risk management plans, post-approval studies) for biosimilar medicines? Is this any different to the requirements for the original Biologics drug?	Post-authorization requirements for biosimilar medicines in Iraq align with general pharmacovigilance practices. This includes monitoring for adverse events, risk management plans, and potential post-approval studies. These requirements are not significantly different from those for original biologics, emphasizing safety and ongoing compliance.

Are there specific policies and requirements in terms of biosimilar medicines labelling in the event of second medical use patents? Is this any different to the requirements for the original Biologics drug?	Specific policies and requirements for biosimilar medicine labeling in the event of second medical use patents are not distinct in Iraq. Biosimilar medicines generally follow the same labeling standards as other pharmaceutical products, focusing on accuracy, safety, and regulatory compliance.
Have there been any significant legal/judicial developments in relation to biosimilars in your country? (Including but not limited to IP, procurement, competition, misleading information campaign, access to reference comparator product)	Significant legal or judicial developments related to biosimilars in Iraq are rare due to the relative infancy of the biosimilar market. The focus is primarily on establishing regulatory frameworks and ensuring safety and compliance in the pharmaceutical industry.
Are there proposals for reform or significant change to the legal, regulatory, procurement of biosimilars? If yes, when are they likely to come into force?	There are no known significant proposals for reform specifically targeting biosimilars in Iraq. Reforms in the pharmaceutical sector generally focus on broader issues like regulatory compliance, safety, and quality control. If future changes are proposed, they will likely be influenced by international trends and efforts to improve healthcare quality and accessibility.

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