Due diligence essentials for responsible pharmaceuticals

The pharmaceutical sector sits at the intersection of scientific innovation, public health, and global commerce, encompassing a complex value chain that spans research and development, raw material sourcing, drug manufacturing, and distribution. It is a significant contributor to GDP and employment across OECD countries and is growing rapidly in response to increasing global demand and the expansion of research and manufacturing capacity in emerging markets. The sector's supply chains involve a diverse range of actors from large integrated pharmaceutical firms and biotechnology companies to contract research organisations and academic institutions. Pharmaceutical supply chains can be associated with environmental, social and governance risks, such as pharmaceutical pollution and water-intensive manufacturing processes, risks on workers in manufacturing processes, patient harm from deceptive marketing, and the proliferation of counterfeit medicines. This case study examines the sector's key characteristics, salient risks and impacts, and the opportunities and challenges that companies face in implementing risk-based due diligence in line with international standards on responsible business conduct.[1] It is targeted at companies in and outside of the pharmaceutical sector who are seeking to understand their exposure to related risks, and also for policymakers and stakeholders seeking to better understand opportunities for promoting effective due diligence in the sector.

Key characteristics of the sector and its value chain

The pharmaceutical sector plays a central role in modern life, intersecting with public health and scientific innovation worldwide. It is a significant employer and a key contributor to gross domestic product (GDP) in numerous OECD countries. The sector is growing rapidly and is anticipated to remain on this trajectory as demand for pharmaceuticals increases and research and development (R&D) and manufacturing capacity migrate and expand in emerging markets (Juneja, Mai and Albu, 2024[1]).

Sector overview

The pharmaceutical sector encompasses the research, development, manufacturing, and distribution of medicines and therapeutic products used to prevent, diagnose, and treat disease. It is one of the most research-intensive industries in the global economy, characterised by long product development cycles, stringent regulatory requirements, and a high degree of globalisation across all stages of the value chain.

The pharmaceutical value chain spans five broad segments. Research and development (R&D) encompasses drug discovery, pre-clinical and clinical testing, regulatory review, and post-marketing surveillance. Raw material sourcing involves the procurement of active pharmaceutical ingredients (APIs) and excipients from biobased, mineral, and fossil-derived sources, as well as packaging materials, through supply chains that are often global and multi-tiered.

The sector is dominated by a relatively small number of large multinational enterprises, commonly referred to as “Big Pharma”, which control significant shares of global R&D investment and branded drug revenues. However, the value chain also includes a large and growing generic manufacturing, as well as a broad ecosystem of contract manufacturers, CROs, distributors, and speciality biotechnology firms. This combination of high market concentration at the top of the value chain and extensive outsourcing and subcontracting throughout creates distinctive responsible business conduct challenges, discussed further in this case study.

Pharmaceuticals are divided into two types based on molecular weight. These include small-molecule pharmaceuticals created from chemical processes (“synthetics”) and large-molecule pharmaceuticals

derived from large-scale cell cultures ("biologicals"). Synthetics include pain relievers such as aspirin, paracetamol and ibuprofen, antibiotics such as doxycycline, and antimalarials such as chloroquine; biologicals, on the other hand, include products such as vaccines, blood components, allergenics, somatic cells, gene therapy tissues and recombinant therapeutic proteins (Makurvet, 2021[2]). They are grown and purified from large-scale cell cultures of bacteria or yeast, or plant or animal cells (WHO, n.d.[3]).

In the pharmaceutical sector, biotechnology R&D is critical to drug discovery. Biotechnology represents a set of innovative technologies derived from biological systems, living organisms or components thereof through modification of their DNA. Biotechnology deploys techniques like genetic engineering, tissue culture and fermentation or new clinical treatments like optogenetics.

Value chain characteristics

The pharmaceuticals value chain can be broadly separated into R&D, the sourcing of raw materials, manufacturing, as well as marketing and distribution.

Table 1. Key activities in the pharmaceutical value chain

Research and development	Raw material sourcing	Drug manufacturing	Packaging and distribution	Marketing
Discovery: Identifying potential drug targets, discovering compounds and early-stage screening for effectiveness.	**Biobased feedstock sourcing:** Sourcing of plant- and animal-based feedstocks, and biobased chemicals.	**Originator pharmaceuticals:** Reinvesting profits into R&D.	**Packaging:** Drug placed into 2-3 layers of packing.	**Marketing:** Direct advertising to health professionals and more marginally (except in the United States) to patients as consumers or through sales to healthcare providers (Barrenho, 2025[4]).
(Pre-)clinical development: Drug testing to evaluate safety, dosage and efficacy.	**Mined feedstock sourcing:** Recovering minerals through methods like open-pit or underground mining.	**Generic manufacturers:** Manufacturing cost-effective alternatives to originator drugs once patents expire, including biosimilars (i.e. lower-cost versions of biologic medicines that have lost patent protection).	**Distribution:** Pharmaceutical companies or their intermediaries transport the pharmaceutical for patient use in healthcare facilities, private practices, pharmacies, etc.	
Regulatory review: Submitting data to regulatory bodies for approval.	**Fossil-based feedstock sourcing:** Sourcing of ingredients derived from petroleum, natural gas, and coal.		**Cold chain management:** Temperature-controlled transport and storage to maintain product efficacy, including ultra-low temperature conditions for biologicals and vaccines.	
Post-marketing surveillance: Monitoring the drug's safety and efficacy once available on the market.				

Research and development

The R&D phase of the pharmaceutical supply chain spans various stages. In the discovery stage, researchers identify potential drug targets and screen compounds for effectiveness. This is followed by pre-clinical testing, where the drug is tested in laboratory and animal models to evaluate its safety, dosage and efficacy. In what can be considered the pharmaceutical supply chain "midstream" segment, the drug enters clinical testing once preclinical testing is successful, involving human trials in three phases[2] to assess its safety, efficacy and optimal use. Drugs undergo regulatory review, where data is submitted to regulatory bodies for approval. Finally, post-marketing surveillance ensures the drug's ongoing safety and effectiveness after it is launched.

R&D in the pharmaceutical sector involves the collaboration of various actors, including large, integrated pharmaceutical companies, specialised biotechnology firms, contract research organisations and academic institutions.

- **Large pharmaceutical firms** often maintain sizable in-house research and development teams focussed on identifying drug targets (i.e. specific molecules such as proteins, genes or RNA, within the body that play a key role in a disease), discovering lead compounds and carrying out preclinical studies. In 2022-2023, the largest 20 pharmaceutical companies worldwide invested USD 145 billion (approximately EUR 140 billion) in R&D (Deloitte, 2024[5]).
- **Biotechnology firms** play a critical role in the early stages of drug discovery. While they may carry out subsequent supply chain functions as well, they typically partner with larger pharmaceutical companies for clinical development and commercialisation.
- **Contract research organisations** (**CROs)** support pharmaceutical companies throughout the R&D process, particularly in clinical trials. They provide third-party services such as managing clinical trial design, patient recruitment and data collection while facilitating regulatory compliance.
- **Universities and academic institutions** drive scientific discovery and pharmaceutical innovation. Researchers in academia conduct fundamental studies to identify new drug targets, explore novel therapeutic mechanisms and generate early-stage data that can be licensed to pharmaceutical companies.

Raw material sourcing

Feedstocks for active and inactive ingredients are sourced from biobased, mineral and fossil sources, each with distinct supply chains and production processes.

Biobased feedstocks are natural raw materials derived from living organisms, including animals, plants and fungi. Animal-derived feedstocks originate most commonly from pigs and cows, but also more rarely from horses, mice, hamsters, chickens and eggs (NHS, 2024[6]). These feedstocks are sourced by pharmaceutical manufacturers or feedstock distributors from farms, slaughterhouses and specialised manufacturers. Plant and fungal-derived feedstocks form another important category, with approximately 25% of prescription pharmaceuticals containing plant-based ingredients (Rates, 2001[7]). Examples of biobased chemicals used in pharmaceuticals include curcumin for anti-inflammatory applications and resveratrol for cardiovascular treatments. Moreover, bioethanol, produced from renewable biomass, is widely used in pharmaceutical formulations.

Mineral-based feedstocks found in pharmaceuticals cover a wide range of uses, such as iron (ferrous sulphate) to treat anaemia, zinc in dermatological solutions, platinum compounds in chemotherapy and lithium salts to treat bipolar disorder. Many pharmaceutical feedstocks derived from mined materials are sourced as clay minerals, i.e. abundant, naturally occurring materials made up primarily of hydrous aluminium silicates. Common commercial clays are mined worldwide, such as bentonite and kaolin. Unlike other minerals, clays require little processing before use – they are typically crushed, ground and shaped before being used in pharmaceutical production (U.S. Geological Survey, 2018[8]).

Fossil-derived feedstocks play a crucial role in pharmaceutical production, serving as catalysts, solvents, precursors, reagents, desiccants and preservatives. Common fossil-based pharmaceutical feedstocks include petrochemical and benzene derivatives such as acetone, hydrochloric acid, acetic anhydride, benzyl chloride and diethyl ether. It is estimated that the fossil pharmaceutical market far outstrips the biobased and mineral-derived market in value; fossil-based inputs accounted for an estimated EUR 916 billion market share, compared to approximately EUR 224 billion for the global biobased pharmaceutical market (Spekreijse et al., 2021[9]). However, concrete data on the production of chemical feedstocks for use exclusively in the pharmaceutical sector is notably weak, due to many chemical feedstocks used in pharmaceutical applications also having applications in the food, cosmetic and

chemistry industries. Beyond active and inactive ingredients, a further set of biobased and mineral-derived raw materials enter the pharmaceutical value chain through packaging.

Drug manufacturing and packaging

Downstream from R&D and raw material sourcing, pharmaceuticals are manufactured for the market before being distributed for patient care. Manufactured pharmaceuticals can broadly be categorised as either original products or generic/biosimilars pharmaceuticals. Manufacturers of original products typically make profits and reinvest a significant portion of their profits into R&D. Manufacturers of generics and biosimilars focus on manufacturing cost-effective alternatives to original drugs once patents expire.

Pharmaceutical manufacturing is heavily diversified among major pharmaceutical companies and a growing industry of third-party providers. Outsourcing is an increasingly common phenomenon, with many different suppliers providing inputs to a larger manufacturer on a contract or order basis globally (Business Wire, 2022[10]).

Following manufacturing, pharmaceuticals are packaged to control quality and prevent contamination or degradation before distribution. Primary packaging is in direct contact with the pharmaceutical product, for example in the form of vials, syringes, blister packs and ampoules. Secondary packaging is consumer-facing and does not touch the pharmaceutical product. Once packaged, pharmaceuticals are distributed to patients via a number of supply chain actors.

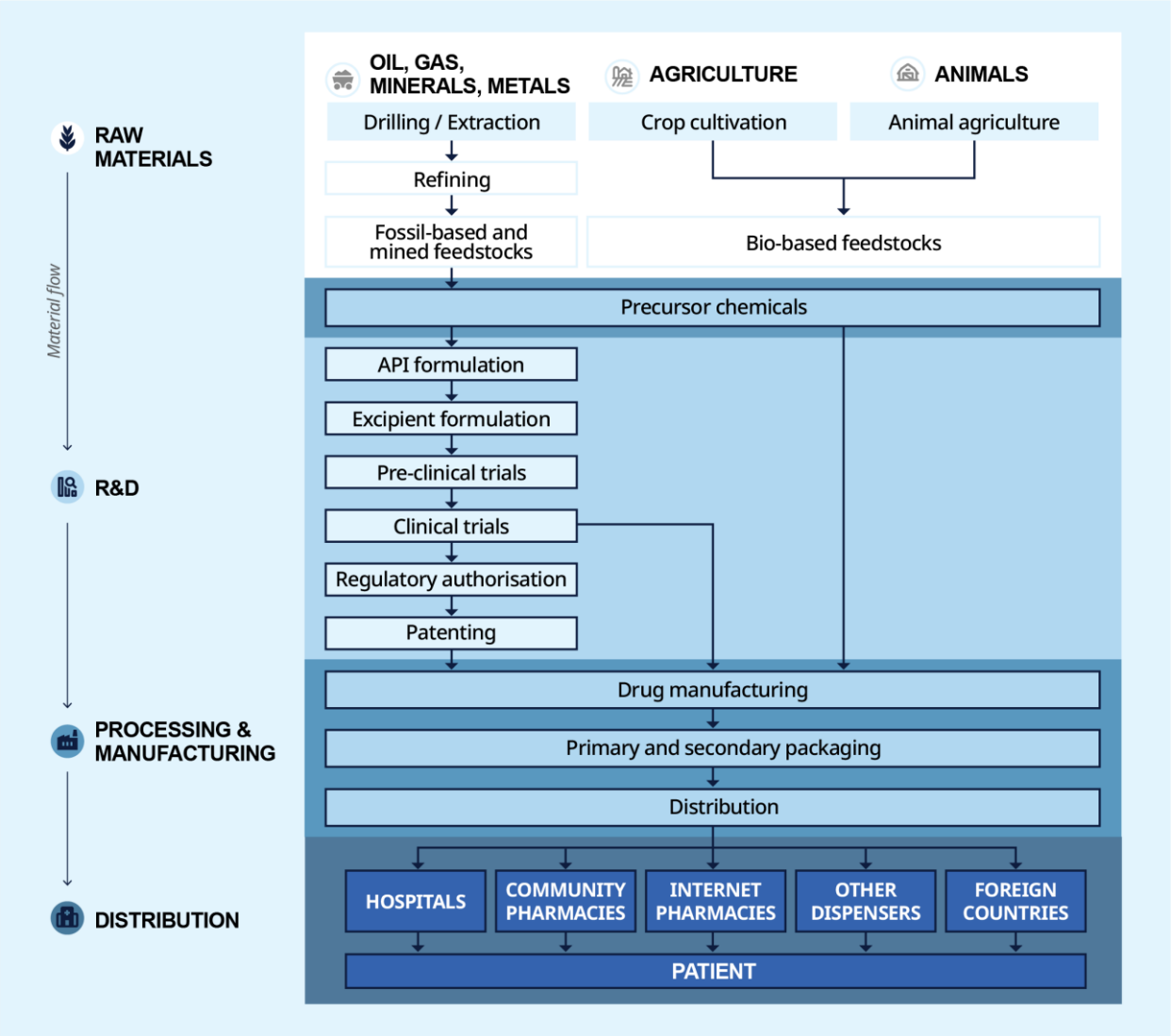
Distribution

Distribution and pricing practices are shaped by countries' varying health systems. In some instances, medical institutions may source directly from manufacturers while in other cases, pharmaceutical wholesalers handle distribution logistics to pharmacies, medical practices, hospitals and clinics (Deloitte, 2019[11]). About 50% of all pharmaceutical logistics require cold chain management, in which drugs are transported in highly controlled environments and kept at ultra-low temperatures (Aitken, Kleinrock and Pritchett, 2023[12]).

Marketing

Major downstream pharmaceutical companies traditionally have large in-house advertising and marketing divisions, though legal requirements on marketing differ significantly between the United States, New Zealand and other OECD countries. Estimates show that major pharmaceutical companies in the United States are spending up to USD 6 billion on direct-to-consumer marketing (Distefano et al., 2023[13]). Marketing to doctors, pharmacists and other healthcare providers takes place using a process called "detailing", i.e. representatives explaining the benefits and uses of specific drugs, often at promotional events and through testimonies from paid clinicians. Outsourcing of marketing functions to third party contractors is increasingly common in the pharmaceutical industry (Grandview Research, 2024[14]).

Figure 1. Pharmaceutical value chain



Regulatory developments

The pharmaceutical sector is highly regulated worldwide, with a strong focus on health and safety and traceability in the international movement of pharmaceutical products between jurisdictions. Supply chain traceability is critical in the pharmaceutical sector to avoid infiltration by illicit actors and negative impacts on patient health. Regulators such as the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) are promoting traceability through legislation such as the US Drug Supply Chain Security Act (2013) and the EU's Falsified Medicines Directive (2011/62), both mandating different serialisation and antitampering measures along the pharmaceuticals supply chain.

International organisations and standard setters also work to standardise their efforts, including through forums like the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and multilateral organisations like the World Health Organization (WHO). The WHO develops guidance and standards on the quality, safety and efficacy of pharmaceutical products such as the Good Manufacturing Practices (GMP) and Good Distribution Practices (GDP) standards that comprehensively address the supply chain operations associated with the preparation and distribution of pharmaceutical products.

Salient impacts associated with the sector

Environmental impacts

Intensive use of water resources

Pharmaceutical manufacturing is highly water intensive. Water is a crucial component of drug production as a solvent and for vaccine cultivation (Gadipelly et al., 2014[15]). Water standards for drug discovery and production are strictly controlled by national and regional pharmacopoeia and include various grades of highly purified water, which are associated with significant energy use. Water is also used as steam for sterilisation, drying and air humidification. While there have been technological advances in water circularity and waste reduction through techniques like reverse osmosis and closed-loop dry cooling systems, the industry remains reliant on water as an essential input for manufacturing (Strade, Kalnina and Kulczycka, 2020[16]).

Water pollution

Pharmaceutical pollution is an emerging environmental issue, with over 2 000 active pharmaceutical ingredients (APIs) produced globally at a scale of around 100 000 tonnes per year (OECD, 2019[17]). These substances, alongside active metabolites (byproducts left over after the drug is metabolised), enter the environment through human and veterinary use, industrial discharge, and improper disposal. Designed to be stable and biologically active, APIs are difficult to remove using conventional wastewater treatment methods, even in highly regulated settings. As a result, pharmaceutical residues have been detected in water bodies and soils worldwide, particularly near manufacturing hubs, and are linked to adverse effects on wildlife (Thompson and Vijayan, 2022[18]). These risks highlight the need to integrate environmental considerations into pharmaceutical research and development.

Waste and environmental footprint

Pharmaceutical manufacturing and wholesale generate significant amounts of waste. A key driver of this impact is the sector's limited circularity, with widespread reliance on single-use, disposable, and individually packaged products (Shelton, 2023[19]). Most pharmaceutical packaging, such as blister packs, syringes, and inhalers, is made from composite or hazardous materials that may be incompatible with mainstream recycling systems. (Dobers et al., 2024[20]). Although some innovative efforts are emerging to reduce packaging waste and improve recyclability, no large-scale circular solutions currently exist.

Animal mistreatment

Concerns of animal mistreatment in the pharmaceutical sector are primarily linked to the use of animal-derived feedstocks and animal testing practices. Animal feedstocks, particularly from pigs or cows, are common in the formulation of pharmaceutical APIs and excipients, particularly for products such as gelatine capsules, vaccines and certain stabilisers. Animal testing is ubiquitous in early-stage drug development as it allows researchers to understand safety, efficacy, dosing, toxicity, side effects and how the drug is absorbed, distributed, metabolised, and excreted (ADME). In many jurisdictions, preclinical animal testing is mandated before trials can run on human subjects. It is estimated that over 190 million animals are killed in laboratory testing annually worldwide (Cruelty Free International, n.d.[21]), raising concerns over animal welfare and ethics, however responsible sourcing practitioners have noted that ethical progress and regulatory controls over the last 20 years has reduced the prevalence of this risk (US Food and Drug Adminstration, 2025[22]; European Medicines Agency, n.d.[23]).

Social impacts

Consumer health

Consumer health risks in the pharmaceutical sector arise from several distinct, though sometimes overlapping, sources. A first category concerns adverse drug reactions under appropriate use, where even correctly prescribed and administered medicines can cause unintended harm, underscoring the importance of rigorous post-marketing surveillance and pharmacovigilance systems (i.e. the system by which the safety of medicines is monitored after they have been approved and are in use by patients). A second category concerns misuse, diversion, and dependency risks associated with specific classes of medicines, particularly controlled substances. These risks are heavily shaped by national prescribing practices, regulatory environments, and the presence of illicit markets, and are therefore not uniform across jurisdictions. A third category concerns deceptive marketing practices, which can exacerbate both of the above risks. Off-label marketing (i.e. the promotion of pharmaceutical products for unauthorised patients, unapproved conditions, or unproven dosages) can encourage inappropriate prescribing and expose patients to harm, particularly where regulatory oversight of marketing practices is weak.

As many as 1 in 10 hospitalisations in OECD countries may be caused by a medication-related event and as many one in five inpatients experience medication-related harms during hospitalisation (de Bienassis et al., 2022[24]). Together, costs from avoidable admissions due to medication-related events and added length of stay due to preventable hospital-acquired medication-related harms total over USD 54 billion in OECD countries. This figure is equivalent to 11% of total pharmaceutical spending across 31 OECD countries for which data are available.

Dependency and diversion risks represent a further dimension of consumer harm. Sixty million people struggle with the addictive effects of opioids globally, and more than 100 000 people die annually from opioid overdoses, many of them involving fentanyl (The Lancet Regional Health – Americas, 2023[25]).

Under-regulated consumer-facing marketing in some jurisdictions may further encourage vulnerable populations to request costly, potentially ineffective pharmaceuticals from healthcare providers while overprescription of medications by doctors may exacerbate these risks. Conversely, the affordability of pharmaceuticals and access to treatment remains a significant challenge, as high drug prices in certain regions make essential treatment inaccessible for vulnerable populations, further complicating the healthcare landscape.

Poor manufacturing practices and inadequate quality controls over raw material inputs can also result in severe harm to consumers. Risks to consumer health can also arise from the use of ingredients that pass regulatory scrutiny at the time of approval but are later found to cause harm (Hayward, 2025[26]).

Human rights violations in manufacturing and packaging

Adverse impacts on workers may occur at any stage of the supply chain, from the extraction of raw materials to the production of drugs through their distribution. Reports of worker exploitation in pharmaceutical packaging plants in certain geographies have included workers being paid below minimum wage and denied formal employment contracts, migrant workers lacking legal protections, long working hours, and lack of access to health insurance (Abbott et al., 2024[27]). Of the 180 audits conducted as part of the Pharmaceutical Supply Chain Initiative (PSCI) platform, worker health and safety were the areas with the most findings in 2023 (PSCI, 2023[28]).

Indigenous Peoples' Rights

According to the WHO, around 40% of pharmaceutical products today draw from nature and Indigenous traditional knowledge, including aspirin, artemisinin, and childhood cancer treatments (WHO, 2023[29]). However, concerns have been raised about the use of such knowledge without adequate recognition,

informed consent or fair benefit-sharing with Indigenous communities. In some cases, natural compounds informed by traditional practices may be patented without acknowledging their origins. Furthermore, the commercialisation of medicinal plants can contribute to environmental pressures such as overharvesting, which may not only threaten biodiversity but also limit Indigenous Peoples' continued access to traditional medicinal resources. The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity is an international agreement which aims at sharing the benefits arising from the utilisation of genetic resources in a fair and equitable way (UN, 2010[30]).

Adverse impacts in human clinical trials

Human clinical trials, while essential for advancing medical knowledge and drug development, can have significant adverse impacts on participants. The World Medical Association's Declaration of Helsinki (1964) outlines the ethical principles that should govern human trials, emphasising the need for informed consent and the protection of participants' well-being. However, impacts associated with trial participation may not always be clearly communicated, particularly to vulnerable populations such as children, the elderly, those with limited literacy or indigent individuals. These groups may face difficulties in understanding the potential health risks and the implications of their involvement. Furthermore, breaches of privacy, including accidental data leaks, unauthorised third-party access, and poor encryption of electronic health records, expose participants to further harm.

Governance impacts

Corruption and bribery

In some jurisdictions, pharmaceutical companies may be exercising undue influence over regulators through bribery and other forms of corruption (OECD, 2023[31]). Research by Transparency International attests to significant expenditures by the pharmaceutical industry on lobbying, estimated to reach tens of millions of US dollars annually by both industry groups and individual companies (Transparency International, 2016[32]). Specific patient groups that seek healthcare solutions for complex issues and are unable to secure adequate public funding or other resources for their causes may be particularly susceptible to undue influence exerted by pharmaceutical companies.

Beyond lobbying, direct bribery of healthcare officials and medical professionals remains a serious corruption risk in the pharmaceutical sector (Sommersguter-Reichmann and Reichmann, 2024[33]). This can involve illicit payments in exchange for the approval of pharmaceutical products, preferential treatment in procurement processes, or influence over regulatory decisions. Kickbacks have also been documented and can take various forms, such as payments to doctors for prescribing certain drugs, financial incentives for referring patients to specific treatments or services, or "upcoding" by which healthcare providers bill insurers for more expensive procedures or medications than those provided.

Counterfeits, illicit trade and digital threats

Pharmaceutical counterfeiting remains a serious risk to consumer health and safety, particularly in contexts where regulatory oversight is weak or enforcement capacity is limited. Counterfeit pharmaceuticals may include tampered, expired, or improperly stored products, all of which can have severe consequences for patients. These risks are further compounded when fraudulent products are introduced into legitimate supply chains, sometimes facilitated by bribery or other governance issues. Substandard or falsified antimalarial medicines are estimated to cause up to 116 000 deaths annually in sub-Saharan Africa alone (WHO, 2022[34]). Illicit actors may also exploit pharmaceutical supply chains for criminal purposes, including the trafficking of dangerous substances under the guise of legitimate products.

The complexity and fragmentation of pharmaceutical supply chains also create vulnerabilities to cyber threats and malicious interference. The sector's heavy reliance on outsourcing across all stages of production and distribution can expose even well-regulated systems to disruption.

Key considerations for due diligence

Challenges

Complex and multi-tiered supply chains

The pharmaceutical sector operates with highly complex and multi-tiered supply chains that span across various geographies, production facilities and intermediaries. Pharmaceutical manufacturing involves numerous inputs sourced across different geographies and production facilities. For example, an mRNA COVID-19 vaccine requires some 270 constituent materials, sourced from as many as 70 suppliers (EY, 2022[35]). Resulting sub-contracting practices result in significant visibility challenges. Pharmaceutical Supply Chain Initiative (PSCI) supply chain audits indicate that firms may often lack visibility over suppliers and may fail to conduct adequate due diligence, even when sourcing from conflict- or sanction-affected geographies (PSCI, 2023[28]).

Transparency limitations

Intellectual property (IP) protection is a core aspect of the pharmaceutical industry, given the competitive advantage that patents and proprietary formulations provide. This strong emphasis on IP rights can be a significant barrier to transparency and the sharing of critical supply chain data during due diligence efforts. It is also a key driver of high prices and contribute to the lack of affordability and availability of drugs.

Pharmaceutical companies may fear that revealing information about their sourcing practices, manufacturing processes or ingredient formulations may lead to the risk of IP theft or exploitation by competitors. This secrecy often extends to purchasers of drugs and intermediaries, such as group purchasing organizations (GPOs), who "generally have little or no information linking the drug products they buy, or contract for, with the specific sites where they were manufactured" (FDA, 2019[36]). As a result, the reluctance to disclose supply chain information can impede the full assessment of social, environmental, and ethical risks within the production and sourcing processes.

Concerns about protecting IP may lead to a lack of trust between companies and stakeholders (e.g. NGOs, investors), complicating collaborative efforts to improve industry-wide due diligence standards and limiting the effectiveness of transparency initiatives.

Leverage limitations

Leverage within the pharmaceutical industry may be limited vis-à-vis key suppliers such as API manufacturers. APIs are central to the production of most pharmaceutical products, and many pharmaceutical companies rely on a limited number of specialised suppliers for these components. This reliance on a limited pool of API manufacturers may reduce the leverage that pharmaceutical companies have to ensure responsible business practices, particularly in areas such as labour standards and environmental sustainability. This may deter companies from taking action in cases where due diligence practices and supplier engagement are necessary.

Challenges associated with downstream due diligence

Downstream due diligence in the pharmaceutical sector presents significant challenges, particularly in identifying and mitigating impacts associated with the improper use and misuse of medications (de Bienassis et al., 2022[24]). Once pharmaceuticals leave the manufacturer's control, they pass through

complex distribution networks, including wholesalers, retailers and healthcare providers. This may make it challenging to ensure that medications reach the intended end-users safely and are used as prescribed. Issues such as diversion to unauthorised markets and misuse pose serious risks, including both intentional misuse and drug abuse and unintentional misuse due to lack of education or improper labelling.

Opportunities

Heightened global attention to pharmaceutical supply chain issues

The COVID-19 pandemic highlighted vulnerabilities of global pharmaceutical supply chains, highlighting the potential health impacts associated with dependence on a few key suppliers and the geopolitical issues associated with trade restrictions and political instability (OECD, 2024[37]). As a result, there is growing recognition that supply chain visibility is not only critical for public health but also a strategic geopolitical interest. Countries are increasingly prioritising secure, transparent, and diversified pharmaceutical supply chains. This may incentivise robust supply chain mapping and supplier due diligence.

Existing traceability requirements and systems

In many jurisdictions, pharmaceutical companies are already legally required to implement traceability systems to ensure the integrity and safety of the drug supply chain. As a result, traceability technologies, such as serialisation and track-and-trace systems are already commonplace and integrated into various phases of the pharmaceutical supply chain (Haji et al., 2021[38]). These technologies allow for the unique identification of each product, enabling its movement through the supply chain to be tracked and monitored in real time. This existing traceability infrastructure can be leveraged in exercising effective due diligence, e.g. through the identification of high-risk suppliers and choke points.

Industry-led initiatives and collective action

Collaborative approaches to supply chain auditing, responsible sourcing, and capacity building among pharmaceutical companies and their suppliers are beginning to emerge in the sector, for example through the Pharmaceutical Supply Chain Initiative (PSCI). Collective auditing and shared risk assessments reduce the burden on individual companies and suppliers and can raise baseline standards across the sector more efficiently than company-by-company approaches. Another example, Rx-360, focusses more specifically on supply chain security and product integrity, operating a shared audit programme designed to reduce the risk of counterfeit and substandard medicines entering the supply chain. Additionally, given the sector's heavy reliance on contract manufacturers, there is an opportunity for originator companies to use collective action and joint leverage constructively, to support supplier capacity building on environmental, labour, and quality standards rather than simply auditing. This mirrors approaches already documented in the garment and minerals sectors.

Related OECD sources

The OECD has developed various resources to support businesses carrying out due diligence:

- OECD Due Diligence Guidance for Responsible Business Conduct
- OECD Guidelines for Multinational Enterprises on Responsible Business Conduct
- OECD e-learning Academy on Responsible Business Conduct

These resources can be supported by sector specific research, including:

- Securing Medical Supply Chains in a Post-Pandemic World
- The economics of medication safety

References

Abbott, J. et al. (2024), "Country of Origin of Medical Products and Risk of Labour Rights Abuse: A Cross-Sectional Analysis Using Four Procurement Datasets", *Cureus*, Vol. 16/2, p. e54258, https://doi.org/10.7759/CUREUS.54258. [27]

Aitken, M., M. Kleinrock and J. Pritchett (2023), *Outlook for medicine use and spending through 2027: Impact on the pharmacy sector*, https://www.iqvia.com/-/media/library/scientific-posters/fip-global-outlook-poster-vertical-orientation_final.pdf. [12]

Barrenho, E. (2025), *Assessing the impact of promotion and advertising regulations on biosimilar uptake*, OECD Publishing, https://doi.org/10.1787/c69f54b2-en. [4]

Business Wire (2022), *Indian Pharmaceutical Contract Manufacturing Market Report 2022: Low Manufacturing Cost, Easy Availability of Skilled Workers, and Well-Established Certified Plants Driving Growth*, https://www.businesswire.com/news/home/20221019005693/en/Indian-Pharmaceutical-Contract-Manufacturing-Market-Report-2022-Low-Manufacturing-Cost-Easy-Availability-of-Skilled-Workers-and-Well-Established-Certified-Plants-Driving-Growth---ResearchAndMarkets. [10]

Cruelty Free International (n.d.), *Facts and figures on animal testing*, https://crueltyfreeinternational.org/about-animal-testing/facts-and-figures-animal-testing. [21]

de Bienassis, K. et al. (2022), *The economics of medication safety: Improving medication safety through collective, real-time learning*, OECD Publishing, https://doi.org/10.1787/9a933261-en. [24]

Deloitte (2024), *Global pharma companies' return on R&D investment increases after record low*, https://www.deloitte.com/uk/en/about/press-room/global-pharma-companies-return-on-rd-investment-increases-after-record-low.html. [5]

Deloitte (2019), *The role of distributors in the US health care industry*, https://www2.deloitte.com/content/dam/Deloitte/us/Documents/life-sciences-health-care/us-hda-role-of-distributors-in-the-us-health-care-industry.pdf. [11]

Distefano, M. et al. (2023), "Association Between Drug Characteristics and Manufacturer Spending on Direct-to-Consumer Advertising", *JAMA*, Vol. 329/5, pp. 386-392, https://doi.org/10.1001/JAMA.2022.23968. [13]

Dobers, K. et al. (2024), "Carbon footprint of package leaflets", *Pharm. Ind.*, Vol. 86/1, pp. 91-97, https://doi.org/10.24406/publica-2592 (accessed on 30 March 2025). [20]

European Medicines Agency (n.d.), *Regulatory acceptance of new approach methodologies (NAMs) to reduce animal use testing*, https://www.ema.europa.eu/en/human-regulatory-overview/research-development/ethical-use-animals-medicine-testing/regulatory-acceptance-new-approach-methodologies-nams-reduce-animal-use-testing#:~:text=animal%20use%20testing-,Regulatory%20acceptance%20of%2. [23]

EY (2022), *Pharma supply chains of the future*, https://www.ey.com/content/dam/ey-unified-site/ey-com/en-gl/insights/life-sciences/documents/ey-pharma-supply-chains-of-the-future-004317-22gbl.pdf. [35]

FDA (2019), *Drug Shortages: Root Causes and Potential Solutions*, https://www.fda.gov/media/131130/download?attachment. [36]

Gadipelly, C. et al. (2014), "Pharmaceutical industry wastewater: Review of the technologies for water treatment and reuse", *Industrial and Engineering Chemistry Research*, Vol. 53/29, [15]

pp. 11571-11592, https://doi.org/10.1021/IE501210J/ASSET/IMAGES/MEDIUM/IE-2014-01210J_0011.GIF.

Grandview Research (2024), *Pharmaceutical Contrac Sales Organizations Market Size, Share & Trends Report*, https://www.grandviewresearch.com/industry-analysis/pharmaceutical-contract-sales-organizations-market-report. [14]

Haji, M. et al. (2021), "Critical Success Factors and Traceability Technologies for Establishing a Safe Pharmaceutical Supply Chain", *Methods and Protocols*, Vol. 4/4, p. 85, https://doi.org/10.3390/MPS4040085. [38]

Hayward, C. (2025), "Thousands in UK sue Johnson & Johnson over talcum powder cancer risks", *BBC News*, https://www.bbc.com/news/articles/c797wv928g8o. [26]

Juneja, M., L. Mai and N. Albu (2024), *The Economic Impact of the Global Pharmaceutical Industry*, https://www.ifpma.org/wp-content/uploads/2024/11/2024_WifOR_Economic_Impact_Global_Pharmaceutical_Industry_Report.pdf. [1]

Makurvet, F. (2021), "Biologics vs. small molecules: Drug costs and patient access", *Medicine in Drug Discovery*, Vol. 9, p. 100075, https://doi.org/10.1016/J.MEDIDD.2020.100075. [2]

NHS (2024), *Medicines containing or derived from Animal Products*, https://www.dchft.nhs.uk/wp-content/uploads/2024/03/Medicines-Derived-from-Animal-Products-March-2024.pdf. [6]

OECD (2024), *Securing Medical Supply Chains in a Post-Pandemic World*, OECD Publishing, https://doi.org/10.1787/119c59d9-en. [37]

OECD (2023), *Health at a Glance 2023: OECD Indicators*, OECD Publishing, Paris, https://doi.org/10.1787/7a7afb35-en. [31]

OECD (2019), *Pharmaceutical Residues in Freshwater: Hazards and Policy Responses*, OECD Studies on Water, OECD Publishing, Paris, https://doi.org/10.1787/c936f42d-en. [17]

PSCI (2023), *Annual Report 2023*, https://pscinitiative.org/resource?resource=2368. [28]

Rates, S. (2001), "Plants as source of drugs", *Toxicon*, Vol. 39/5, pp. 603-613, https://doi.org/10.1016/S0041-0101(00)00154-9. [7]

Shelton, J. (2023), *Sounding the alarm about disposable plastic in the health care industry*, https://news.yale.edu/2023/10/10/sounding-alarm-about-disposable-plastic-health-care-industry. [19]

Sommersguter-Reichmann, M. and G. Reichmann (2024), "Untangling the corruption maze: exploring the complexity of corruption in the health sector", *Health Economics Review*, Vol. 14/1, pp. 1-16, https://doi.org/10.1186/S13561-024-00530-6/TABLES/10. [33]

Spekreijse, J. et al. (2021), *Bio-based value chains for chemicals, plastics and pharmaceuticals : a comparison of bio-based and fossil-based value chains*, https://op.europa.eu/publication-detail/-/publication/54a54654-9292-11eb-b85c-01aa75ed71a1. [9]

Strade, E., D. Kalnina and J. Kulczycka (2020), "Water efficiency and safe re-use of different grades of water - Topical issues for the pharmaceutical industry", *Water Resources and Industry*, Vol. 24, p. 100132, https://doi.org/10.1016/J.WRI.2020.100132. [16]

The Lancet Regional Health – Americas (2023), "Opioid crisis: addiction, overprescription, and insufficient primary prevention", *The Lancet Regional Health - Americas*, Vol. 23, https://doi.org/10.1016/j.lana.2023.100557. [25]

Thompson, W. and M. Vijayan (2022), "Antidepressants as Endocrine Disrupting Compounds in Fish", *Frontiers in Endocrinology*, Vol. 13, p. 895064, https://doi.org/10.3389/FENDO.2022.895064. [18]

Transparency International (2016), *Corruption in the pharmaceutical sector: Diagnosing the challenge.*, https://ti-health.org/wp-content/uploads/2016/09/29-06-2016-Corruption_In_The_Pharmaceutical_Sector_Web-2.pdf. [32]

U.S. Geological Survey (2018), *Mineral Resource of the Month: Clay Minerals*, https://www.earthmagazine.org/article/mineral-resource-month-clay-minerals/. [8]

UN (2010), "Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity", *Treaty Series*, https://treaties.un.org/pages/ViewDetails.aspx?src=TREATY&mtdsg_no=XXVII-8-b&chapter=27. [30]

US Food and Drug Adminstration (2025), *FDA Announces Plan to Phase Out Animal Testing Requirement for Monoclonal Antibodies and Other Drugs*, https://www.fda.gov/news-events/press-announcements/fda-announces-plan-phase-out-animal-testing-requirement-monoclonal-antibodies-and-other-drugs. [22]

WHO (2023), *Traditional medicine has a long history of contributing to conventional medicine and continues to hold promise*, https://www.who.int/news-room/feature-stories/detail/traditional-medicine-has-a-long-history-of-contributing-to-conventional-medicine-and-continues-to-hold-promise. [29]

WHO (2022), *WHO Director-General's opening remarks at the Regional Committee side event on Fighting Substandard and Falsified Medicines in Africa: A Collaborative and Integrative Approach*, https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-fighting-substandard-and-falsified-medicines-in-africa---23-august-2022. [34]

WHO (n.d.), *Biologicals*, https://www.who.int/health-topics/biologicals. [3]

Notes

[1] The sector was chosen for a case study based on a previous study by the OECD to identify and synthesise insights from key resources on the prevalence of issues covered by the OECD Guidelines for Multinational Enterprises (the OECD Guidelines) across industry sectors. To complement this analysis, the OECD further conducted an expert survey to attain a broad picture of the perceived association with Responsible Business Conduct (RBC) issues across sectors.

[2] Phase 1 focusses on evaluating the safety of the drug in a small group of healthy volunteers, determining the appropriate dosage and identifying side effects. Phase 2 involves a larger group of patients to assess the drug's effectiveness and monitor its safety in the target population. Phase 3 tests the drug in an even larger group of patients to confirm its efficacy, monitor side effects, and compare it to existing treatments.

Photo credits: © SweetBunFactory / Getty Images