# Roadmaps to Nature Positive → Foundations for the pharmaceutical sector



World Business Council for Sustainable Development

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# *01.* Nature Action: a business imperative

## Nature Action: 01. a business imperative

#### Nature matters for business

Nature forms the foundation of the global economy, as all businesses rely on it to varying degrees. Societies cannot endure, much less prosper, without the vital services provided by the natural world – clean air, water, food and a stable planetary system.

And yet, the ongoing and accelerating depletion of nature is one of the greatest risks that humanity faces today. Humanity is using double the resources that the Earth can regenerate each year.<sup>1</sup> This unsustainable use, coupled with changes in land and sea use, pollution and greenhouse gas (GHG) emissions, is driving unprecedented levels of biodiversity loss.<sup>2</sup>

The loss of nature is already affecting businesses, both directly and indirectly. Industries with high to moderate dependence on nature - those that depend significantly on the extraction of resources from land, freshwater and oceans – account for more than half of global GDP.<sup>3</sup>

Addressing the climate crisis, restoring nature and protecting biodiversity are interconnecting and mutually reinforcing objectives. Effective climate change mitigation requires protecting and restoring natural systems, ensuring they are healthy and resilient.

Efforts to protect and restore nature must actively involve local communities and stakeholders. This principle is a key aspect of the Kunming-Montreal **<u>Global Biodiversity Framework</u>** (GBF), particularly under Target 19, which stresses the importance of inclusive and participatory action. Engaging communities and stakeholders fosters the development of locally adapted solutions, ensuring that conservation and restoration efforts are effective and enhance the resilience and livelihoods of those who depend on these ecosystems. Similarly, Target 13 focuses on sharing of benefits from genetic resources, including digital sequence information (DSI) and contributing to the GBF's successful implementation by recognizing the role played by those who protect biodiversity and preserve traditional knowledge.4

The Convention on Biological Diversity (CBD) decision on the fair and equitable sharing of benefits from the use of DSI on genetic resources established a voluntary fund to enable companies to share benefits arising from the use of DSI. Known as the Cali Fund, the indicative contribution rates are currently under review – along with several other elements – as part of ongoing intergovernmental discussions to refine benefitsharing mechanisms. In alignment with international

frameworks, the pharmaceutical sector engages with access and benefit-sharing processes as required by the Nagoya Protocol and the CBD, supporting efforts to ensure fair and transparent contributions to biodiversity conservation.

As global discussions on benefit-sharing continue to evolve, it will be important to refine mechanisms to ensure that they do not hinder innovation while recognizing the contributions of countries and communities that provide access to these resources. Strengthening collaboration among researchers, industry, and stakeholders will be critical to fostering the sustainable and responsible use of genetic materials, ensuring alignment with international biodiversity frameworks and equitable development goals.

The solutions needed are not incremental adjustments to existing business models. Achieving WBCSD's Vision 2050 and enabling more than 9 billion people to live well and within planetary boundaries requires the transformation of societies and economies.<sup>5</sup>

#### Nature risks have shifted global policy

Nature has rapidly risen on the agenda for both the real economy (production, transportation, and selling of goods and services) and the financial services sector, including investors. The world can no longer overlook the escalating risks related to nature loss, prompting policymakers, regulators, investors, businesses, consumers and greater society to unite in demanding urgent response and action.

The adoption of the GBF in 2022 was a pivotal moment for nature action, often referred to as a "Paris Agreement" for nature. It elevates nature to the same prominence as climate on the global political agenda. The GBF sets a clear global ambition to halt and reverse biodiversity loss by 2030, outlining 23 targets to guide action across governments, businesses and civil society. Among these, Target 15 specifically calls for companies to assess, disclose and reduce biodiversity- and naturerelated risks and negative impacts, highlighting the critical role of businesses in achieving this goal. A corporate accountability system for nature is also rapidly emerging to support and catalyze credible and impactful business action on nature, building on a similar system for climate.

In the space of voluntary corporate accountability frameworks, the Science Based Targets Network (SBTN) released the initial set of science-based targets for freshwater and land in 2023 and plans to release guidance for ocean science-based targets in 2025. In 2024, the SBTN also released a new suite of enabling materials and integrated its updated technical guidance into its target-setting process. Additionally, the Taskforce on Nature-related Financial Disclosures (TNFD) published its initial recommendations for naturerelated financial disclosures in 2023, along with sectorspecific guidelines for various industries, including the biotechnology and pharmaceutical sectors.

In addition to voluntary frameworks, mandatory requirements also hold companies accountable for their impacts on nature and biodiversity. For example, the European Sustainability Reporting Standards (ESRS), under the Corporate Sustainability Reporting Directive<sup>7</sup> (CSRD), cover key nature-related topics (pollution, water and marine resources, biodiversity and ecosystems and the circular economy), with the overall objective to help companies prevent or mitigate negative impacts on the environment. In addition, the Corporate Sustainability Due Diligence Directive (CSDDD), which became part of European Union (EU) legislation in June 2024, mandates due diligence and public disclosure of the social

and environmental impacts of business operations and supply chains. In addition, the **EU Deforestation** Regulation (EUDR) proposed in June 2023 and due to come into effect in December 2025, requires companies placing specific commodities and products on the EU market to ensure they are deforestation-free and meet strict traceability and due diligence obligations.

As part of the CSRD, the EU taxonomy for sustainable activities also plays a critical role by providing a standardized classification system for sustainable economic activities, prioritizing the channeling of investments into economic activities that support the green transition, in line with the European Green Deal objectives.<sup>8</sup> Similarly, regulators in a number of jurisdictions have indicated they will adopt the International Sustainability Standards Board (ISSB) Standards and make them mandatory in the near future, including the General Requirements for Disclosure of **Sustainability-related Financial Information** (IFRS S-1) and Climate-related Disclosures (IFRS S-2).9

> $\rightarrow$  The SBTN targetsetting process has five steps:

Assess, Prioritize, Set targets, Act and Track.6

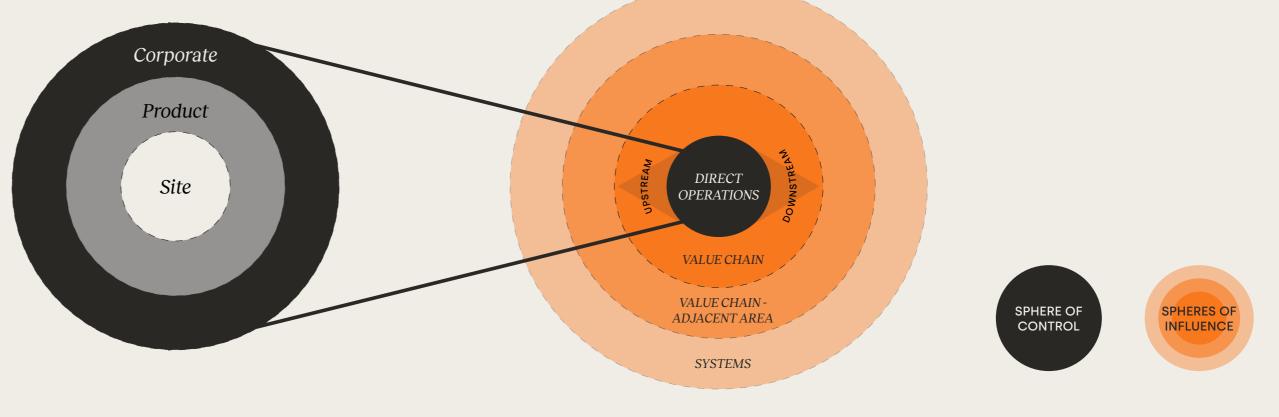
# Nature positive and current business approaches

Stakeholders widely acknowledge the term "nature positive" as a global goal to halt and reverse nature loss by 2030 and achieve full recovery by 2050, emphasizing efforts to restore and sustain biodiversity, ecosystems and natural resources. The GBF mission statement captures this goal, indicating it is a strategic international plan aimed at guiding collective actions to safeguard biodiversity and ensure the long-term recovery of ecosystems.<sup>10</sup> Individual companies can contribute to this shared goal by adopting an approach to nature positive throughout their spheres of control and influence, including in their direct operations, value chains and priority locations (see Figure 1).

To help guide business action on nature, WBCSD, SBTN, TNFD, the World Economic Forum and Capitals Coalition have developed a consistent approach to help businesses effectively address their relationship with nature: the <u>high-level business actions on nature to</u> <u>Assess, Commit, Transform and Disclose (ACT-D)</u>. This framework guides businesses through available tools, frameworks and initiatives to **assess** their impacts and dependencies on nature, **commit** to ambitious targets, **transform** their practices and **disclose** relevant naturerelated information. The ACT-D Framework forms the backbone of this Roadmap, with the structure organized based on its core action areas. By adopting this approach, businesses can establish an ambitious, credible and strategic approach to contribute toward a nature-positive future (see Figure 2).

To support the implementation of the ACT-D Framework, WBCSD collaborated with Business for Nature's <u>It's</u> <u>Now for Nature</u> campaign, a global campaign to rally all businesses to act on nature, to develop the <u>Nature</u> <u>Strategy Handbook</u>. The Handbook helps companies acknowledge the value of nature to their business;

Figure 1: Sphere of control and spheres of influence relevant for corporate target-setting



Source: Adapted from SBTN (2020). Science-Based Targets for Nature Initial Guidance for Business

identify, assess and measure their impacts and dependencies on nature; set transparent, time-bound, science-based targets; take actions to address their key impacts and dependencies and transform their businesses; and publicly disclose performance and other relevant nature-related information.

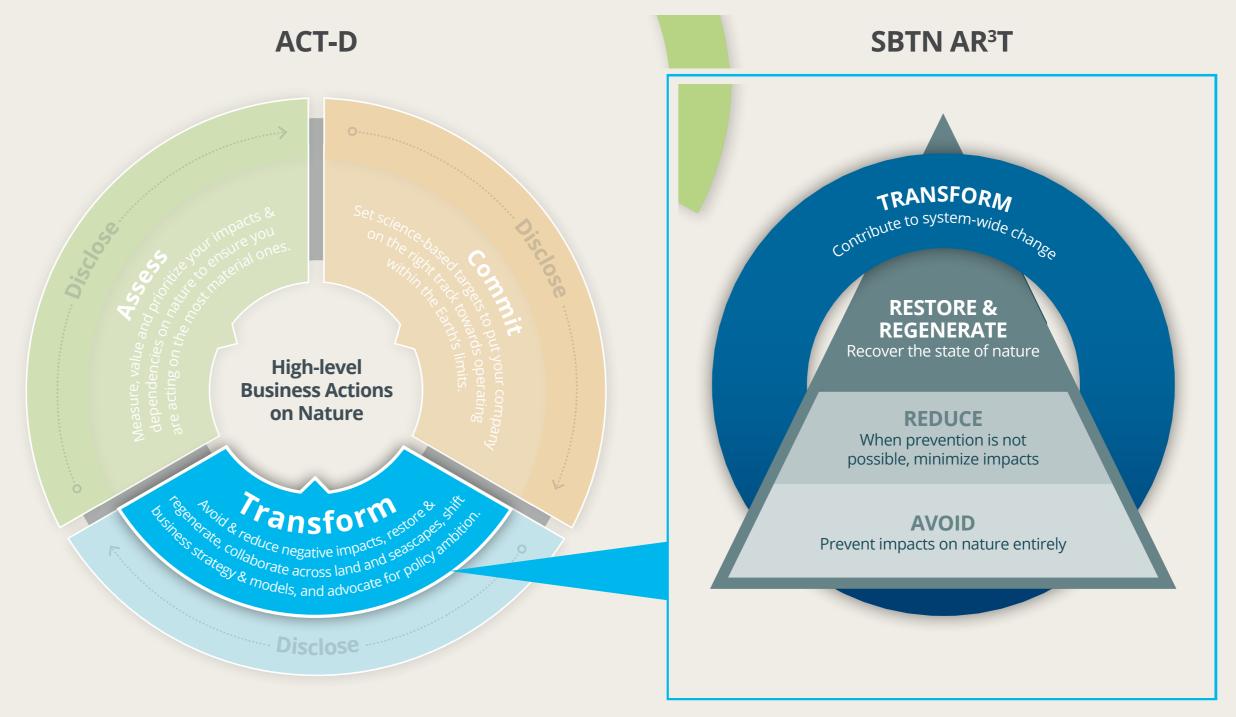
#### WBCSD approach to nature positive for business

Nature positive is gaining traction in the business community. WBCSD bases its approach to it on key principles shared by leading organizations in this space, including SBTN, TNFD, Business for Nature and others.

To credibly contribute to nature-positive outcomes, it is important to both understand and mitigate the company's impacts on nature and to maximize the positive effects of regenerative and restorative actions. Companies can design and guide their actions using SBTN's mitigation hierarchy, the <u>Avoid,</u> <u>Reduce, Regenerate & Restore, Transform (AR3T)</u> <u>Action Framework</u> (see Figure 2), which suggests that individual companies must accelerate action to halt nature loss while simultaneously bringing back more nature. Actions that reduce harm will help collectively reverse nature loss by 2030, while restorative, regenerative and transformative actions are critical to achieving full recovery by 2050.

In summary, companies should be holistic and transparent in the approach they take to assess, commit, transform and disclose and, in doing so, highlight their contributions towards a naturepositive future – rather than claiming to be nature positive themselves.<sup>11</sup>

# Figure 2: SBTN's Action Framework (AR3T of the "Transform" stage of ACT-D



Source: Business for Nature (2023). Priority actions towards a nature-positive future

Figure 2: SBTN's Action Framework (AR3T) defines the hierarchy of actions that companies can put in place as part

#### Catalyzing critical business action in support of nature positive

Despite recent progress, corporate actions on nature are still falling short given the urgency of the crisis. Many companies lack experience in managing the inherent complexities of nature and navigating the rapidly evolving corporate accountability frameworks. The **World Benchmarking Alliance** (WBA) 2024 assessment of more than 800 major global companies found that only 5% have assessed the impact of their operations on nature, while less than 1% have evaluated their dependencies on nature. It is worth noting that the WBA rated the pharmaceuticals and biotechnology sector as one of the leading industries in nature reporting.<sup>12</sup>

To respond to the challenges companies face, <u>WBCSD's</u> <u>Roadmaps to Nature Positive</u> unite peers from the same sectors or economic systems to create a shared agenda that accelerates nature-positive ambitions, actions and accountability. In addition to this Pharmaceutical Roadmap, Roadmaps are currently available for four different systems – <u>agri-food</u>, <u>forest products</u>, <u>built</u> <u>environment</u> and <u>energy systems</u>. The Roadmaps form part of a broader collaboration with the World Economic Forum and Business for Nature (BfN) under the <u>It's Now</u> <u>for Nature</u> campaign to scale-up business action on nature and contribute towards a nature-positive world by 2030. This Foundations for the Pharmaceutical Sector Roadmap provides essential guidance for pharmaceutical companies to develop and enhance their nature strategies. It emphasizes value chain materiality screening, identifies priority actions to systematically avoid and reduce negative impacts, outlines optimal restoration and regeneration approaches and supports preparation for both voluntary and mandatory disclosures.

In 2025, as part of the second phase of the Pharmaceutical Roadmap, we will tie the priority actions to halt and reverse nature loss identified in this Roadmap to a set of prioritized metrics to measure and report their impact in alignment with key voluntary and regulatory frameworks. We will assess each metric based on a prioritization criterion, as well as its degree of alignment with key voluntary and regulatory frameworks such as TNFD and CSRD. We will make the prioritized metrics available to users (meaning sustainability practitioners) by the end of 2025 through a Nature Metrics Portal.

# O2. Introducing the Roadmap for the pharmaceutical sector

# 02. Introducing the Roadmap for the pharmaceutical sector

#### **Context: Importance of nature to the** pharmaceutical sector

Nature is critical to human health and well-being, providing air, water, food and the raw materials needed to manufacture medicines and medicinal compounds. The pharmaceutical sector, which exists to improve human health and quality of life, also relies on nature for many of its operations and innovations, such as water for the production of biological medical products like vaccines.

However, negative impacts from many human activities are driving significant environmental changes, including increases in invasive species, changes in land and sea use, climate change, pollution and direct exploitation of natural resources. All of these collectively contribute to nature and biodiversity loss.<sup>13</sup> This loss, in turn, is endangering the health of people and the planet, potentially affecting everyone and everything. The World Health Organization (WHO) estimates that nearly 14 million people die each year from environmental health risks,<sup>14</sup> highlighting the interconnection between human health and environmental well-being.

The healthcare sector, while focused on improving human health, also contributes to environmental

impacts. For example, the sector is responsible for some 5% of global GHG emissions, accentuating the industry's impact on the natural environment.<sup>15</sup> While the continuing advancement of medical technology has contributed to the extension of global life expectancy from 46.5 years in 1950 to 71.2 years in 2023,16 the processes involved in developing, manufacturing and delivering medicines also contribute to climate change and nature loss. We describe these impacts further in Stage 1: Assess (materiality screening) in this Roadmap.

Environmental changes are also impacting human health, particularly – but not only – among marginalized populations who are most vulnerable to the effects of climate change. The interconnectedness of ecosystems means that disruptions in nature and climate change often lead to a range of adverse consequences for human health, for example:

→ **Emergence of zoonotic diseases**: As habitat loss brings society in closer proximity to nature, there is an increasing emergence of new zoonotic diseases. Landuse change has already contributed to the emergence of more than 30% of new diseases reported since 1960.<sup>17</sup> Research has shown that climate change further amplifies these risks by driving wildlife into closer contact with human populations.<sup>18</sup>

- $\rightarrow$  Changes in vector-born, waterborne and noncommunicable diseases: Climate change and biodiversity loss are driving shifts in disease patterns. Rising temperatures and altered ecosystems are expanding the range of vector-borne diseases, like malaria and dengue, into previously unaffected regions. Factors such as flooding and poor sanitation exacerbate waterborne illnesses, while higher temperatures and air pollution contribute to the increase and changing pattern in non-communicable diseases such as respiratory and cardiovascular conditions.
- → **Climate change and migration**: Extreme weather events, rising sea levels and prolonged droughts are displacing millions of people annually. This forced migration increases the spread of infectious diseases, strains healthcare systems and worsens living conditions in overcrowded areas.
- → **Mental health impacts**: The compounding effects of natural disasters, such as wildfires, floods and hurricanes, are leading to significant mental health challenges. These impacts can contribute to increased rates of anxiety, depression and trauma among individuals vulnerable to the effects of nature loss and climate change.<sup>19</sup>

Zoonotic diseases are infectious diseases transmitted between species from animals to humans or from humans to animals.

Introducing the Roadmaps for the pharmaceutical sector *continued* 

The pharmaceutical value chain encompasses a variety of processes. These range from sourcing raw materials from organic (agricultural and natural systems) and inorganic (mined metals and minerals) compounds, and disposal of pharmaceutical ingredients. Their impacts and dependencies on nature vary in scale and potential materiality. As the sector grows and develops novel therapies to improve patient outcomes, its increasing impacts and dependencies on nature are putting added pressure on the environment.

The pharmaceutical sector has a complex value chain that brings unique challenges related to identifying and managing nature-related impacts and dependencies. Nature impacts are particularly difficult to address when they occur deep in the value chain, such as sourcing raw materials (both organic and inorganic) and managing the safe and compliant disposal and end-of-life treatment of pharmaceutical products. In these areas, the traceability and management of nature-related impacts and dependencies can be difficult to achieve.

Additionally, to maintain the highest medical efficacy and safety standards, these companies manufacture medicines and medical devices in energy- and waterintensive facilities where single-use items are prevalent. Although innovative solutions to minimize environmental impacts are increasing, making changes to products and processes requires time and partnerships with regulators to ensure patient safety. Leading and peer companies are already developing collaborative solutions to some of these challenges.



#### Benefits of contributing towards nature-positive outcomes

Contributing towards nature-positive outcomes offers a range of benefits for companies, from enhancing business resilience to safeguarding critical resources and building long-term value. Transforming business models to align with a nature-positive future both helps mitigate environmental impacts and creates opportunities in innovation, cost reduction, supply chain resilience and strengthened stakeholder engagement (refer to Stage 1.3 Assess risks and opportunities for further details on opportunities). Frameworks that promote actions to halt and reverse nature loss while achieving operational and strategic benefits, like SBTN's AR3T - Avoid, Reduce, Restore & Regenerate and Transform guidance – can steer this transformation.

For example, the pharmaceutical industry's reliance on horseshoe crabs – a vital resource in testing the quality of vaccines and injectable medications to ensure patient safety<sup>20</sup> – illustrates the urgent need for a comprehensive approach. This dependency on horseshoe crab blood has contributed to population declines, which in turn affect other species, such as migratory shorebirds that rely on their eggs as a critical food source.<sup>21</sup> Based on SBTN's AR3T framework, companies can address this issue at multiple levels: transitioning to synthetic alternatives helps mitigate reliance on natural populations (avoid), while improved animal husbandry can minimize immediate impacts

(reduce). Habitat restoration projects can further strengthen ecosystems (restore and regenerate), while fostering long-term partnerships between pharmaceutical companies, conservation organizations and regulatory bodies helps ensure sustainable management (transform).

While transitioning to synthetic alternatives is promising, these efforts are part of a regulated space, requiring time for implementation.

Another example of nature-positive practices is the adoption of green chemistry principles, which enhances manufacturing efficiency while reducing environmental impacts.<sup>22</sup> These principles – a set of <u>12 guidelines</u> – focus on minimizing waste, using safer materials and improving the efficiency of chemical processes. Again, SBTN's AR3T framework promotes different types of actions to address the issue, such as:

- → **Avoiding** the use of hazardous chemicals by transitioning to safer, more sustainable alternatives;
- → **Reducing** environmental impact through more efficient manufacturing processes that eliminate/ minimize waste and resource consumption;
- → **Restoring** and regenerating ecosystems by sourcing raw materials from sustainable and regenerative practices, thus reducing ecosystem pressure;

→ **Transforming** the sector by fostering partnerships across the value chain to drive innovation in sustainable chemistry, ensuring long-term environmental and operational resilience.

It is important to note that pursuing such initiatives may involve trade-offs, particularly when balancing net-zero and nature-positive goals. For example, while using bio-feedstocks can help lower carbon emissions, it may also place pressure on ecosystems if companies do not sustainably manage their sourcing practices.

Beyond operational benefits, nature-positive practices can also promote social equity and cultural preservation. Natural systems inspire many medicines, highlighting the importance of conserving biodiversity and respecting traditional knowledge. Supporting these efforts preserves ecosystems and empowers Indigenous Peoples and local communities, ensuring a balanced approach that protects cultural heritage, nature and biodiversity. In this way, companies can align with nature-positive practices while building resilience and fostering innovation in a nature-positive future.

Introducing the Roadmaps for the pharmaceutical sector continued

#### Scope of the Roadmap

This Roadmap covers the full value chain of the pharmaceutical sector (SICS CODE: HC-BP), from inputs such as raw material production to manufacturing, processing and the distribution of pharmaceutical products, as well as patient use and end-of-life disposal.

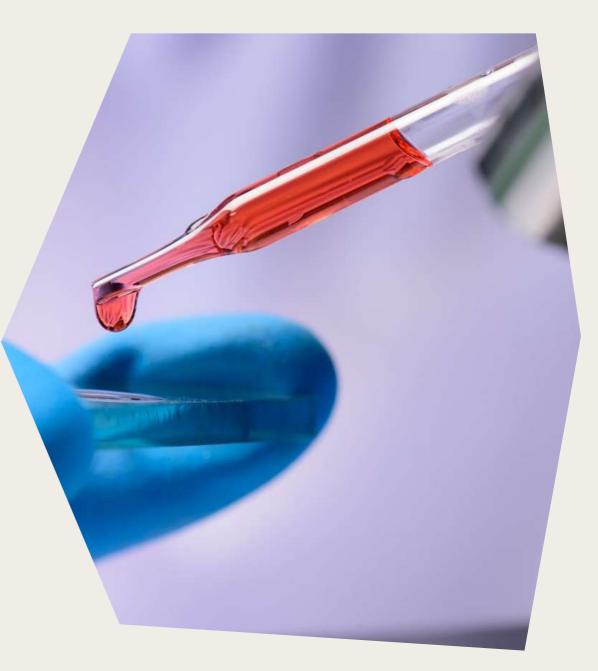
#### Pharmaceutical value chain

The pharmaceutical value chain is complex and involves numerous industries. Every pharmaceutical company will have a unique model, leveraging a combination of suppliers, contract development and manufacturing organizations (CDMOs), partners and their own operations to fulfil their business function. Figure 3 provides a high-level overview of the key industries and business activities that are present and have a notable interface with nature. These activities span four main phases - upstream, direct operations, downstream and end-of-life.

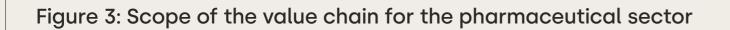
→ The upstream value chain in the pharmaceutical sector covers activities and processes that occur prior to the manufacturing of pharmaceutical products. These activities are critical as they enable the production of high-quality medicines and vaccines and ensure that the entire supply chain operates efficiently.

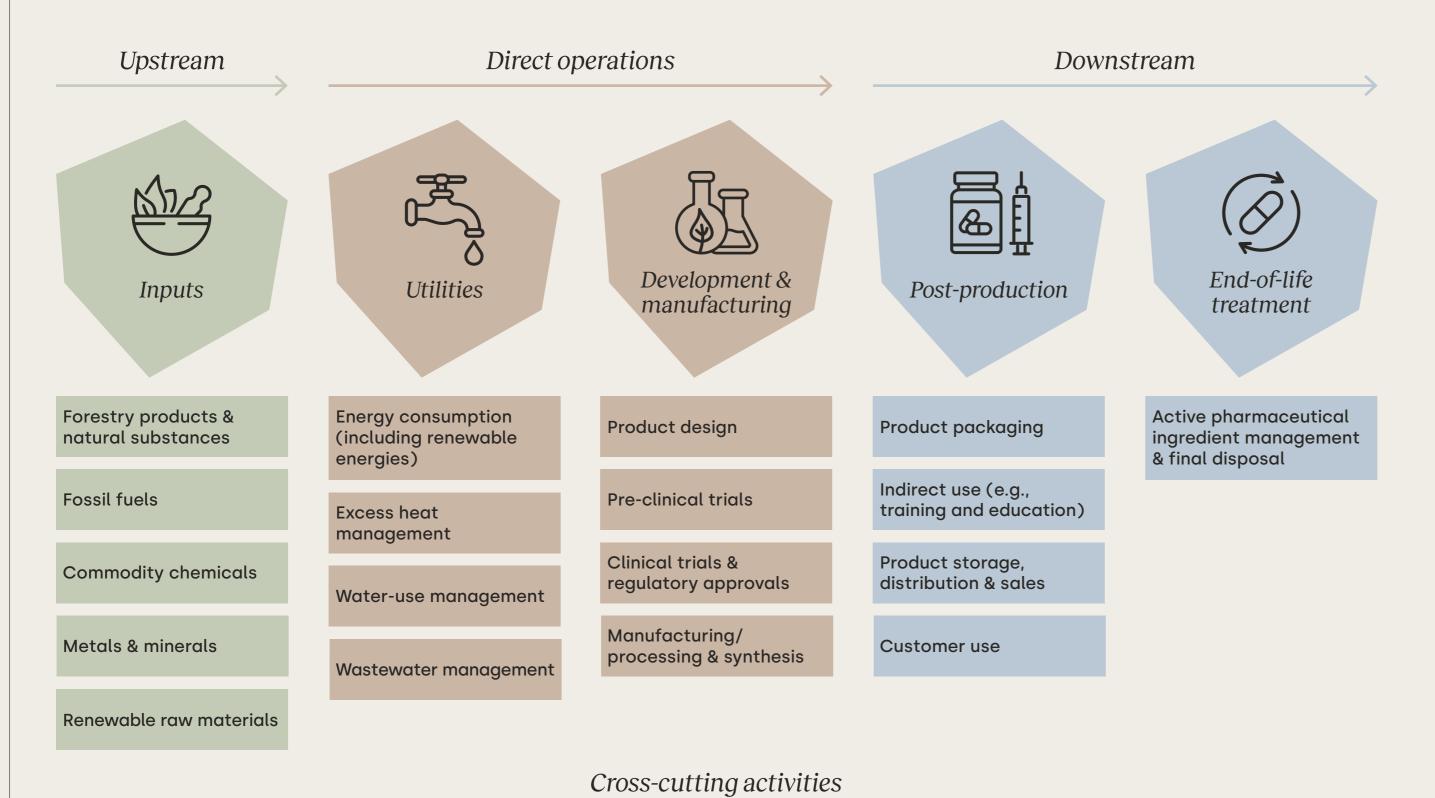
- → The direct operations component of the pharmaceutical value chain encompasses the core activities and processes directly involved in the development, quality control and clinical trialing of pharmaceutical products. These operations are crucial for consistent production and in ensuring the efficacy, safety and quality of the medicines and vaccines produced.
- → The downstream and end-of-life aspects of the pharmaceutical value chain include the activities associated with packaging, distribution and the use of the finished product manufactured in the direct operations phase. This also encompasses the activities occurring when pharmaceutical products expire or after patients have used them. This phase is crucial to ensuring the safe, compliant and environmentally responsible disposal of pharmaceutical products. When unused medicines expire, it is necessary to dispose of them appropriately. Considerations in this phase include recycling methods and waste management processes specifically tailored to handle the unique waste generated as part of the pharmaceutical value chain.

We have split the activities in the pharmaceutical value chain by value chain phase, with cross-cutting activities displayed at the bottom of the **Figure 3**.



→ The pharmaceutical value chain does not include specific considerations for veterinary medicine; however, some of the lessons learned in this document may be of use to actors in that industry.







Water infrastructure (supply and treatment)



Waste management and recycling



Infrastructure and land use

# O3. Foundations for the pharmaceutical sector

# 03. Foundations for the pharmaceutical sector

Transitioning towards a nature-positive future requires companies to adopt a structured and comprehensive approach to integrating nature into their strategies and operations. This section outlines the key stages of the ACT-D Framework, detailing how companies can assess their dependencies and impacts on nature, establish measurable commitments to mitigate these impacts and dependencies, implement transformative actions across their value chains and transparently disclose their progress.

We use the commodities referred to in this section as examples to contextualize the intersection between the pharmaceutical sector and nature. It is important to note that the relevance of naturebased commodities varies across companies and often closely ties to their specific product portfolios.

#### $\rightarrow$ Stage 1: Assess (materiality screening)

Materiality screening is at the heart of an impactful nature journey as it enables a business to identify the most material nature-related impacts and dependencies. These will require the setting of actions and credible targets in response. Materiality for specific topics can differ depending on a pharmaceutical company's business model and portfolio. To ensure a comprehensive approach, companies should conduct a materiality screening as a participatory process, involving input from experts and stakeholders in and outside the company. from within and outside the company.

#### Assess: Foundations – Sector materiality screening

A materiality screening based on typical sectoral impacts and dependencies can help identify and prioritize the parts of the business with the highest potential risks and opportunities (R&O). By making dependencies, impacts, risks and opportunities (DIROs) more explicit and tailoring them to the specific activities and characteristics of a company, the business case for action on nature offering benefits for the business, communities and other stakeholders – becomes clearer and more compelling.



Foundations for the pharmaceutical sector *Continued* 

A materiality screening should take place at the beginning of a company's journey efforts to build a nature strategy by identifying priority DIROs that will require a more in-depth assessment. More advanced companies can also perform a materiality screening process to check that they have covered their priority issues. This step is feasible regardless of sector, geographic location or level of sustainability. Emerging and existing voluntary and regulatory frameworks – including CSRD, SBTN and TNFD – require double materiality screening and define additional requirements for how companies should complete a materiality assessment.

The foundational steps to "Assess" include:

- Scope and locate: Identify the company's main sectors, sub-sectors and parts of the value chain and their location;
- 2. Evaluate impacts and dependencies: Prioritize potentially high impacts and dependencies on nature that are typical for the business and associated value chains for further assessment, using the details in this Roadmap as a starting point;
- **3. Assess risks and opportunities:** Assess associated risks and opportunities for the business and for key stakeholders in order to prioritize further action.

Taking these steps will support organizations in identifying and prioritizing locations, value chain phases, dependencies, impacts, risks and opportunities that may require deeper analysis.

Organizations using this Roadmap will have differing maturity levels when it comes to nature-related risk and opportunity assessments and will experience differing regulatory requirements depending on the jurisdictional locations in which they operate. Outside of mandatory reporting requirements, nature-related materiality assessments can vary in scope depending on available resources. For example, some organizations starting out on their nature journey may decide to limit the scope of their initial materiality assessments to their direct operations. However, the most pharmaceutical companies are likely to find the majority of their nature-related DIROs in their value chains.<sup>23</sup> The expectation is for companies to work towards expanding the scope of their assessments to encompass the entire value chain as their maturity develops and more internal resources and data become available. It is important to note that pharmaceutical companies captured under the CSRD will need to expand the scope of assessments and disclosure to their wider value chain to comply with the EU directive.<sup>24</sup>



#### $\rightarrow$ SBTN recommends a materiality assessment

but does not explicitly require the application of a double materiality approach. However, the framework inherently considers both impact materiality and financial materiality. CSRD and TNFD explicitly incorporate a double materiality approach in their frameworks.

#### Stage 1.1 - Scope and locate

Identify the company's main sectors and sub-sectors, key parts of the value chain and their locations.

#### Why do this:

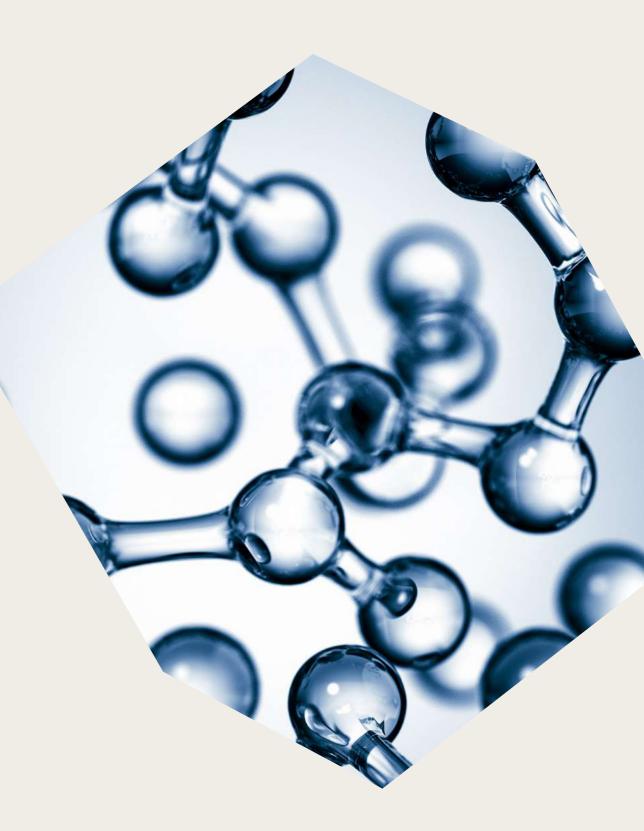
Primary impacts and dependencies on nature may result from production processes that are part of direct operations, upstream (including the sourcing of raw materials) or downstream due to product use or disposal. To accurately identify and address the most significant risks and opportunities across the value chain, it is important to consider the activities that occur at each phase. This step is essential in locating potentially material nature-related DIROs across the value chain and developing a credible and impactful approach to nature-positive practices.

#### What to do:

- → Identify sectors and sub-sectors that represent activities throughout the value chain to support the identification of typical impacts and dependencies in the following stages of the materiality assessment (see Figure 3 for an illustration of the pharmaceutical value chain).
- → Identify the geographies where these activities occur to help determine interfaces with nature across the direct operations and value chain.

This is a critical step for companies in the pharmaceutical sector given the complexity of their value chains. From the upstream supply of active pharmaceutical ingredients (APIs), which are the active components in a drug responsible for the therapeutic effects and excipients derived from agriculture or fossil fuels by the chemicals sector, to the processing of wastewater at production sites and downstream by the utilities sector, the impacts of pharmaceutical production can vary across geographies. In turn, the nature-related DIROs linked to each sector or subsector can vary widely. Companies should first consult sections 2.1 and 2.2 of the TNFD Biotechnology and pharmaceuticals sector guidance and SBTN step 1 and **<u>2 guidance</u>**. If the company is in scope to disclose under CSRD, the **ESRS** guidance to develop a credible approach will also inform their materiality assessment, actions and commitments. These resources cover key questions, considerations and data needs and recommend tools and resources.

**Excipient**: A substance formulated alongside the active ingredient of a medication.



### Stage 1.2 - Evaluate impacts and dependencies

Prioritize high impacts and dependencies on nature typical for the business and associated value chains for further assessment.

In developing this Roadmap, we used the Exploring Natural Capital Opportunities, Risks, and Exposure (ENCORE) tool to assess the pharmaceutical sector's impacts and dependencies on nature. This assessment was further refined through stakeholder consultations with industry peers to prioritize the key impacts and dependencies outlined in the Roadmap.

While this provides a starting point to help companies identify potential material impacts in their value chains, it is a generalized assessment. Companies may identify additional priorities based on their specific business models and resulting materiality, and should conduct further risk and opportunity evaluations before using the list to inform priority actions and targets.

> → \*The ENCORE database helps financial institutions and companies better understand their relationships with nature by providing detailed insights into potential impacts and dependencies. Additional information on its methodology can be found in the UNEP-WCMC **Explanatory Note**.

#### Why do this:

A credible listing of typical nature-related impacts and dependencies for the pharmaceutical sector offers a strong starting point for company-level materiality assessments, especially for companies less familiar with the complexities involved. The pharmaceutical sector is heavily regulated, which can mean that changes to business practices can take time. This increases the urgency for these companies to identify material impacts, so that they can map them and implement the resulting actions and stakeholder engagement. By refining the nature-related impacts and dependencies through their risk assessment processes, companies can deepen their understanding of the nuanced relationships between their operations, value chain and nature. Given the multifaceted aspects of nature, which can vary depending on a company's maturity level, it is crucial to prioritize the most significant impacts and dependencies as a starting point. This approach supports the prioritization of strategically important issues and reduces exposure to greenwashing accusations by ensuring that data and a strategic process underpin any action.

#### What to do:

- $\rightarrow$  Identify potentially material impacts and dependencies:
  - Develop a list of typical nature-related impacts and dependencies based on existing materiality screening tools, in addition to expertise from the business and its partners;
  - Begin by prioritizing impacts and dependencies rated as potentially "high" or "very high" risk for further analysis and action and increase the scope of the screening as maturity develops over time

#### Nature-related impacts

The list below of nature-related impacts for the pharmaceutical sector aims to provide a starting point to support companies in identifying potential material impacts in their value chains. The list is the result of a generalized assessment and will require further risk and opportunity evaluation before companies use it to inform the development of priority actions and targets. Table 1 provides a more complete list of potential naturerelated impacts, where they are likely to occur in the value chain and their potential materialities. To protect and enhance ecosystems, we encourage businesses in the pharmaceutical sector to direct their efforts toward addressing the most significant impacts that their operations and value chains have on nature, namely (not ordered by priority):

→ GHG emissions: Manufacturing processes, which require specific ambient conditions such as humidity, temperature and sterility, along with company vehicles and purchased energy, all contribute to direct operational GHG emissions.<sup>25</sup> The extent of these emissions depends on the energy sources used to meet these requirements. Additionally, sourcing inputs, product distribution, transport and product use significantly contribute to value chain emissions. GHG emissions are the key driver of climate change. In turn, the Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services (IPBES) identifies them as a direct driver of nature loss. There is significant evidence that rising global average temperatures disrupt weather patterns, which damages or reduces the resilience of ecosystems and the wildlife within.

Foundations for the pharmaceutical sector *Stage 1.2 - Evaluate impacts and dependencies* 

- → Land-use change: The pharmaceutical sector can lead to some changes in land use, particularly in the upstream value chain, through the sourcing of raw materials and intermediary products. For example, companies often derive pharmaceutical compounds used in manufacturing processes from agricultural or forestry-based feedstocks such as palm oil, soy or sugarcane, which can contribute to deforestation, habitat loss and altered land-use patterns. While smaller in scale, land-use change also results from the construction or expansion of manufacturing sites and office facilities. These activities can lead to ecosystem destruction or fragmentation, reducing biodiversity, impairing vital ecosystem connectivity and diminishing resilience to stressors such as climate change.
- → Solid waste: The pharmaceutical value chain generates solid waste, including a variety of materials, some of which may have potentially been in contact with APIs or biological, or genetically modified materials requiring additional considerations for treatment and or disposal. Examples of solid waste include raw material containers for chemicals and solvents, components such as tubes, filters and single-use processing systems, as well as product packaging and distribution devices such as syringes, insulin cartridges, injectors and asthma inhalers. Waste classified as hazardous or clinical presents unique challenges for effective and compliant disposal or re-processing. Incorrect disposal of unused medicines by patients poses unnecessary risks to the environment and waste handlers and can potentially

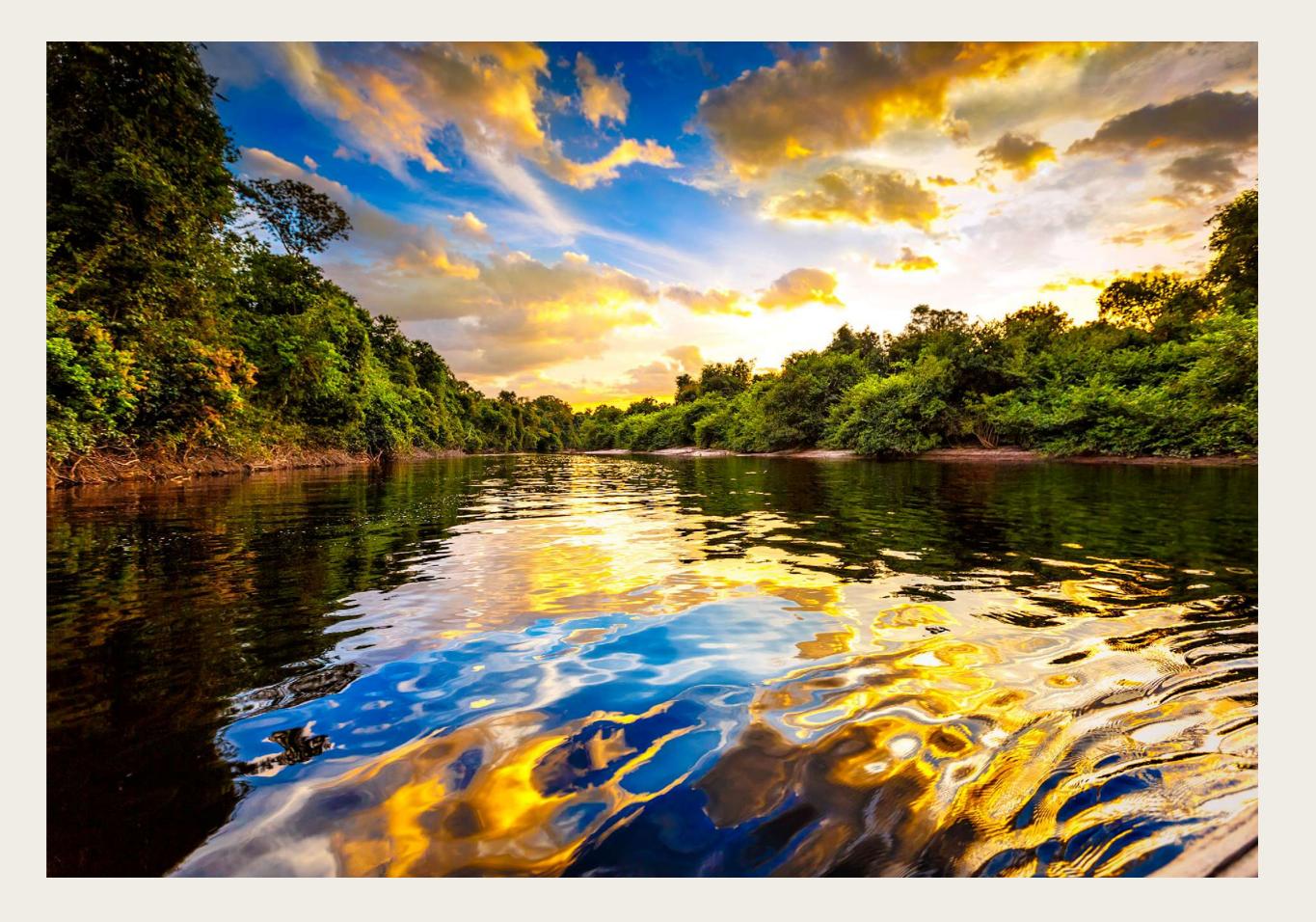
contribute to the presence of APIs in the environment.<sup>26</sup> Additionally, the pharmaceutical sector is one of many contributors to plastic waste and the bioaccumulation of microplastics is increasingly linked to human and animal health impacts, such as metabolic disorders and reproductive toxicity.<sup>27</sup> However, stringent regulations governing the materials used in storage, manufacturing medicine delivery components or devices can make it challenging to introduce more sustainable alternatives. Despite these challenges, there are opportunities for reform, with some regulatory bodies exploring ways to support the adoption of sustainable materials without compromising safety. Additionally, international policies aimed at plastic reduction are likely to drive the industry toward greater adoption of environmentally friendly solutions.<sup>28</sup>



→ Water use: Companies use water as an ingredient in medicines, in production processes (for instance as a solvent or for cooling), in the cultivation or extraction of raw materials, for the cleaning and sterilization of labs and equipment and at the point of product use by consumers and patients.<sup>29</sup> Companies use both groundwater and surface freshwater. The production of specialist and commodity agricultural crops used by the sector can also be water intensive, in addition to the production of APIs, excipients and precursor chemicals. Unsustainable extraction from water sources can increase localized drought risks and risks of flash flooding (prolonged dry weather results in hardened soils, which become impermeable to rainwater, thereby increasing the risk of flash flooding due to increased surface runoff) in water-stressed areas, affecting the resilience of ecosystems and local communities.

Foundations for the pharmaceutical sector *Stage 1.2 - Evaluate impacts and dependencies* 

 $\rightarrow$  Water pollution: The release of APIs (including antibiotics), harmful chemicals and other substances (micro- and nano-plastics, organic carbon sources, nitrates, phosphates, salts, heavy metals, etc.) can occur due to activities across the pharmaceutical value chain, including following patient use, improper disposal of unused medicines, as well as post-use excretion by users.<sup>30</sup> Tight regulations and controls intend to prevent the release of APIs in waterways, such as the EU Water Framework<sup>31</sup> Directive, the EU Environmental Quality Standards<sup>32</sup> and the USA's Clean Water Act.<sup>33</sup> If APIs are not removed through municipal wastewater treatment facilities, they can be released into the environment. Pharmaceuticals in the environment (PIE) and toxic or nutrient pollutants can disrupt ecosystems, for example by affecting species reproduction or contributing to the eutrophication of waterways.<sup>34</sup> Another important element of PIE is the potential contribution to the spread of antimicrobial resistance (AMR) related primarily to the use, overuse and misuse of antibiotics in humans and animals. The presence of sufficiently high levels of antibiotic residues in the environment can promote AMR in pathogens that threaten human, livestock and wildlife populations. The formation and work of the antimicrobial resistance industry alliance represents the life science industry's acknowledgement of this issue and commitment to understanding and minimizing the impact of antibiotics on AMR from emissions across value chains.<sup>35,36</sup>



#### Table 1: Impacts associated with phases of the pharmaceutical sector value chain\*

PBES drivers	Impact drivers (Pressures)	Upstream				<b>Direct Operations</b>	Downstream	Cross-cutting			
of change		Agricultural products <sup>1</sup>	Chemicals <sup>1</sup>	Materials <sup>1</sup>	Energy <sup>1</sup>	Pharmaceutical manufacturing and services <sup>1</sup>	Healthcare <sup>1</sup>	Waste management <sup>1</sup>	Water utilities <sup>1</sup>	Transport and distribution <sup>1</sup>	
Land-/water-/sea-use change	Area of land use	νн	L	М	н	М	L	М	н	М	
	Area of freshwater use	н	N/A	VH	VH	N/A	N/A	N/A	н	М	
	Area of seabed use	н	N/A	VH	VH	N/A	N/A	ND	м	М	
Natural resource use and exploitation	Volume of water use	νн	н	М	М	М	L	М	м	М	
	Other biotic resource extraction (e.g., fish, timber)	VH	N/A	N/A	N/A	VL	N/A	N/A	N/A	N/A	
limate change	Other abiotic resource extraction	N/A	N/A	H <sup>2</sup>	N/A	N/A	N/A	N/A	N/A	N/A	
Pollution	GHG emissions	н	м	М	VH <sup>3</sup>	М	VL	н	н	н	
	Non-GHG air pollutant emissions	νн	н	н	VH <sup>3</sup>	М	L	М	М	VH	
	Toxic soil and water pollutant emissions	н	VH	νн	VH	М	L	М	VH <sup>6</sup>	L	
	Nutrient soil and water pollutant emissions	νн	N/A	νн	N/A	М	ND	М	VH <sup>7</sup>	М	
Invasive species and others	Generation and release of solid waste	νн	М	νн	н	M <sup>4</sup>	М	М <sup>5</sup>	М	М	
	Disturbances (e.g., noise, light)	н	νн	VH	VH	М	L	н	νн	VH	
	Introduction of invasive species	VH	N/A	L	L	L	L	М	∨н	VH	

#### Materiality ratings are based on the ENCORE (July 2024) database.

Refer to the following notes for a description of the superscript numbers in this table.

- \*\*\*"No data" refers to areas for which insufficient data was available to ENCORE to calculate a materiality rating.
- \*\*\*\*"Not applicable" refers to areas where ENCORE has determined an ecosystem service does not apply to a given business activity.

#### Notes:

1. Annex 5.1 outlines the methodology and list of International Standard Industrial Classification (ISIC)-aligned business activities for each component of the value chain. 2. Some, but not all, pharmaceutical companies have identified the impact from the extraction of both biotic and abiotic materials, such as metals, minerals and inorganic salts by mining

- and quarrying, as an impact of note.

- It is also necessary to consider other pollutants, such as salts and heavy metals.
- upstream suppliers.

3. The impact of GHG emissions is significantly lower for pharmaceutical companies that already source most or all their energy from renewable sources, rather than from fossil fuels. 4. The pharmaceutical sector's direct operations strictly manage solid waste due to stringent regulation, minimizing its output.

5. Several industry experts identified plastic waste as a notable impact throughout the value chain, although there was emphasis that, for many, it may be less material than other impacts identified. The industry uses plastics throughout the value chain, for example for lab equipment, protective gear, drug delivery mechanisms, storage, sterile containers and in packaging. 6. They consistently identified the presence of APIs, particularly antibiotics that could contribute to AMR, in the environment as a key downstream impact of pharmaceutical product use.

7. Companies identified nutrient pollution, such as nitrates, phosphates and organic carbon sources, as important for consideration, particularly from agricultural runoff from

#### Nature-related dependencies

Like many sectors, the pharmaceutical sector depends on a number of ecosystem services and assets to operate. The list below of nature-related dependencies for the pharmaceutical sector aims to provide a starting point for companies to identify potential material dependencies in their value chains. The list is the result of a generalized assessment and will require further risk and opportunity evaluation before companies use it to inform the development of priority actions and targets. A more complete list of potential nature-related dependencies, their likely locations in the value chain and their associated materialities is available in Table 2. To understand their relationship with nature, businesses should identify these dependencies that support the evaluation of nature-related risks and opportunities. Businesses in the pharmaceutical sector rely particularly on (not ordered by priority):

→ Water supply: Pharmaceutical manufacturing processes and the use of water as an ingredient for products - such as water for injection (WFI) - depend on a consistent, pure and plentiful freshwater supply.<sup>37</sup> Climate change impacts on precipitation patterns and surface water evaporation, along with increased water consumption due to human activities, can contribute to disrupted and depleted water supplies. Additionally, deforestation and the destruction of habitats, driven by changing land use, disrupt precipitation, water evaporation and flow regulation in basins.<sup>38</sup> This highlights the interconnectedness of biodiversity loss and water supply challenges in these ecosystems.

- → Water purification: The pharmaceutical sector is facing increasing regulation regarding water pollution. Companies therefore adhere to strict systems and protocols to minimize their emission of APIs, harmful substances and other pollutants. However, due to technical limitations, there is strong reliance on the bioremediation and filtration capacity of local ecosystems to manage the effects of the smaller volumes of pollutants released into the environment from activities throughout the value chain.<sup>39</sup> Natural physical and biological processes (such as microbial decomposition) help remediate these pollutants (APIs, harmful substances and other pollutants) and improperly disposed of waste materials from agricultural, industrial and domestic sources.40
- → **Climate regulation**: The pharmaceutical sector has a long, highly varied and complex value chain that depends on a stable climate. Climate hazards have the potential to disrupt crop growing, the mining of key metals and any transportation of these products by air, rail, road and sea. Climate regulation is necessary to prevent outages to manufacturing operations and downstream product delivery. Climatic variability and extremes can also impact health due to associations with extreme temperatures, food insecurity and malnutrition. Additionally, climate change may exacerbate the transmission and spread of certain diseases, such as malaria, by altering the habitat ranges of Anopheles mosquitoes.<sup>41</sup>

- → Genetic material research: Companies can use research models and genetic information from nonhuman organisms and pathogens in research and development to improve the scientific understanding of disease. This can lead to insights and innovations that contribute to the development of new medications, vaccines and improved biotechnology processes. As these genetic and biological resources are part of pharmaceutical research, Target 13 of the GBF covers the fair use, procurement and management of genetic resources. This target aims to ensure equitable access to genetic and biological resources, promoting benefit sharing to support both scientific progress and biodiversity conservation.
- → **Bio-based products**: Materials, chemicals and energy derived from biological resources include wild species (e.g., horseshoe crabs and shark liver) and agricultural products (e.g., biofuels, bioplastics). The sector increasingly relies on biomass inputs for products, production processes and energy generation. For instance, Limulus amoebocyte lysate (LAL), derived from the blood of horseshoe crabs, is a critical bio-based product used to test for endotoxins in pharmaceutical products, ensuring patient safety.

Endotoxins: Harmful substances found in the outer membrane of certain bacteria. When these bacteria break apart, they release endotoxins into the body. If they enter the bloodstream, they can be harmful.

Foundations for the pharmaceutical sector *Stage 1.2 - Evaluate impacts and dependencies* 

Regulatory authorities in certain jurisdictions mandate its use. Similarly, many pharmaceutical products rely on agricultural products such as pharmaceutical-grade starch from crops like corn or potatoes. This starch functions as an excipient in drug formulations, aiding in tablet binding, disintegration and the stabilization of capsules and liquid medications.<sup>42</sup> Additionally, pharmaceutical product transportation and distribution frequently uses bio-based materials like wooden pallets or wood fiber and cardboard boxes. Altogether, this growing reliance underscores the importance of sustainable biomass resources in advancing pharmaceutical innovation and safety.

These dependencies strengthen the business case to invest in the protection and restoration of nature. Companies can consider the materiality screening in <u>Table 1</u> and <u>Table 2</u> as foundational guidance to identify potential impacts and dependencies that each company can adapt to its specific situation. The tables provide the outcomes from an assessment of the supply chain and direct operations of the pharmaceutical sector, consolidating key business activities as defined by ISIC and their respective impact and dependency materiality ratings, according to the July 2024 version of ENCORE.<sup>43</sup> The tables offer companies a starting point that they can further refine according to nuances and circumstances. When refining impacts and dependencies, a company should consider frequency, timeframe and severity.

As companies advance on their nature action journey, they should progressively refine the assessment of their interface with nature through additional metrics and data, which is a specific focus in the second phase of the Roadmap.

The second phase involves a set of nature-related metrics and targets linked to the priority actions for pharmaceutical companies to measure and report on the impacts of the actions over time. We assess each metric based on a prioritization criterion, as well as its degree of alignment with key voluntary and regulatory frameworks such as TNFD and CSRD.

cosystem service	Impact drivers (Pressures)	Upstream				<b>Direct Operations</b>	ect Operations Downstream		Cross-cutting		
category		Agricultural products <sup>1</sup>	Chemicals <sup>1</sup>	Materials <sup>1</sup>	Lifergy	Pharmaceutical manufacturing and services <sup>1</sup>	Healthcare <sup>1</sup>	Waste management <sup>1</sup>	Water utilities <sup>1</sup>	Transport and distribution <sup>1</sup>	
Provisioning	Other provisioning services – animal-based energy	М	N/A	N/A	N/A	N/A	N/A	N/A	N/A	М	
	Biomass provisioning	VH	N/A	VL	N/A	L <sup>4</sup>	N/A	N/A	VL	N/A	
	Genetic material	VH <sup>2</sup>	N/A	N/A	N/A	H <sup>2</sup>	N/A	N/A	N/A	N/A	
	Water supply	VH <sup>3</sup>	М	н	н	H <sup>3</sup>	М	М	М	L	
egulation and	Water purification	VH <sup>3</sup>	М	VH	М	VH³	VH	М	VH	М	
aintenance	Water flow regulation	VH <sup>3</sup>	М	н	Н	H <sup>3</sup>	н	М	н	М	
	Rainfall pattern regulation	VH	М	VH	М	N/A	N/A	М	VH	VH	
	Solid waste remediation	VH	L	М	М	L	М	VH	VH	ND	
	Soil and sediment retention	VH	М	М	М	М	L	VL	М	н	
	Soil quality regulation	VH	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	
	Other regulating and maintenance services – dilution by atmosphere and ecosystems	М	L	М	М	L	N/A	М	М	VL	
	Biological control	н	N/A	VL	N/A	VL	VL	VL	VL	VL	
	Nursery population and habitat maintenance	н	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	
	Pollination	VH	N/A	N/A	N/A	L	N/A	N/A	N/A	N/A	
	Air filtration	н	VL	VL	VL	VL	VL	М	М	VL	
	Flood control	н	М	н	н	М	н	М	н	н	
	Storm mitigation	н	М	М	М	М	н	L	н	н	
	Global climate regulation	VH	VL	н	VH	L	VL	VL	VL	М	
	Local (micro and meso) climate regulation	VH	L	L	М	L	L	L	L	L	
	Noise attenuation	VL	VL	VL	М	VL	VL	VL	VL	VL	
	Other regulating and maintenance services – mediation of sensory impacts (other than noise)	VL	VL	L	L	VL	VL	VL	VL	N/A	
Cultural	Recreation-related services	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	VH	
	Visual amenity services	N/A	N/A	N/A	N/A	N/A	VH	N/A	N/A	VH	
	Education, scientific and research services	VH <sup>2</sup>	N/A	N/A	N/A	VH <sup>2</sup>	N/A	N/A	N/A	N/A	
	Spiritual, artistic and symbolic services	VH	N/A	N/A	N/A	N/A	VH	N/A	N/A	N/A	

#### Table 2: Dependencies associated with phases of the pharmaceutical sector value chain\*

#### Materiality ratings are based on the ENCORE (July 2024) database.

Refer to the following notes for a description of the superscript numbers in this table.

- \*\*"No data" refers to areas for which insufficient data was available to ENCORE to calculate a materiality rating.
- \*\*\*\*"Not applicable" refers to areas where ENCORE has determined an ecosystem service does not apply to a given business activity.

#### Notes:

- 1. <u>Annex 5.1</u> provides the methodology and list of ISIC-aligned business activities for each component of the value chain.
- and development.
- manufacturing, such as the use of water for injection (WFI).
- timber providing paper and cellulose supporting various manufacturing processes.

2. We have identified genetic material as a key dependency for the pharmaceutical sector given the scientific insights that can be derived from nature to support drug discovery, research

3. We defined water use, supply and purity as key dependencies for the reliable production of agricultural inputs, as well as production and cooling processes in pharmaceutical

4. The pharmaceutical sector relies on bio-based products derived from both wild species and agricultural resources. For example, the sector can use squalene from shark liver in certain vaccine formulations, while soy products support antibody production and syrups and other medicines include them. Additionally, bio-based materials play a key role in packaging, with

#### Stage 1.3 - Assess risks and opportunities

Identify how material impacts and dependencies can lead to risks and opportunities for the organization.

#### Why do this:

Increasing numbers of businesses are making the connection between the health of ecosystems and their bottom line. Risks and opportunities originate from business impacts on nature and the associated impacts on stakeholders, as well as corporate and societal dependencies on ecosystem services. TNFD categorizes risks into physical risks (related to material nature-related dependencies), transition risks (arising from changes in regulatory, policy or societal landscapes) and systemic risks (stemming from the breakdown of the entire system rather than failures of individual components). Opportunities can emerge from mitigating nature risks and from innovative market strategies that align with a nature-positive approach.

Annex 5.2 provides more information on naturerelated risks.

#### What to do:

- $\rightarrow\,$  Refine the list of prioritized impacts and dependencies by scoring for potential risks and opportunities based on likelihood versus magnitude of risks and other relevant criteria;
- $\rightarrow$  Engage with stakeholders to refine the list of issues;
- $\rightarrow$  Carry out a further qualitative assessment by considering how DIROs may evolve in the future; TNFD provides different scenarios for consideration.44

The TNFD LEAP (Locate, Evaluate, Assess, Prepare) guidance and Additional sector guidance on Biotechnology and pharmaceuticals contain detailed "how-to" instructions for assessing nature-related risks and opportunities for pharmaceutical companies, including considerations of likelihood, magnitude, speed of onset and other factors; use of nature-related scenarios; and illustrative examples for several phases of the value chain.

Major nature-related risks and opportunities for the pharmaceutical value chain derive from the material dependencies and impacts identified in the sections on nature-related impacts and on nature-related dependencies. We list the key considerations below (refer to Annex 5.2 for the full risks and opportunities table).

#### Physical risks

Acute and chronic upstream risks include soil degradation, water stress and climate change (both at the global and local levels), all of which lower the quality and yield of key agricultural inputs for pharmaceutical manufacturing processes, thereby increasing costs or disrupting supply chains.

Acute risks associated with pharmaceutical manufacturing processes can include deteriorating water quality resulting from the release of APIs, heavy metals and other hazardous chemicals into the environment. Damage to buildings and transport infrastructure can also occur from extreme weather events such as storms or flooding events, which are increasing in frequency and intensity due to climate change.

Typically, organizations are more exposed to physical risks if they have significant dependencies on nature. For example, disruption to or the collapse of an ecosystem may lead to the reduced supply of a key resource or ecosystem service or the potential for a complete loss of that resource or service.

#### **Transition risks**

Transition risks can include lower sales and profits and increased operating costs as domestic and tradebased nature-positive policies come into force, such as deforestation- and conversion-free (DCF) policies. Additionally, there are expectations that the GBF will accelerate the implementation of these policies globally, increasing pressure on companies to align with naturepositive practices. Healthcare providers, patient users and financial institutions may also choose not to purchase from and invest in companies and regions linked to negative environmental issues.

The switch to bio-based materials and pharmaceutical chemical inputs in efforts to reduce the use of fossil fuel-derived products also presents the risk of resource scarcity of such materials if demand outstrips supply. This may also lead in turn to increases in habitat conversion and encroachment as producers seek to remedy this supply deficit.

Typically, significant impacts on nature expose companies to transition risks. For example, companies whose value chain activities involve deforestation may face fines and penalties associated with deforestation- and conversionfree policies and regulations. Similarly, the introduction of the more stringent environmental regulation of levels of water, soil and solid waste pollution may raise capital costs for the upgrading of manufacturing and the necessary waste disposal systems to ensure compliance. The GBF's influence is likely to only reinforce the adoption of such policies, driving further transitions toward sustainable business practices and highlighting the risks for companies failing to adapt.

#### Systemic risks

If current rates of nature loss continue, some ecosystems may cross irreversible tipping points, with far-reaching economic and social impacts, up to and including the collapse of natural or financial ecosystems.<sup>45</sup> For example, the impacts of the pharmaceutical sector as a part of the total global impact of human activity could contribute to systemic ecological decline, leading to chronic drought, the desertification of tropical forests and savannahs, or the loss of keystone species. This decline can become irreversible, causing ecosystem collapse, which may undermine food production systems and lead to the breakdown of local or national economies.

#### Nature-related business opportunities

In alignment with frameworks such as TNFD, CSRD and SBTN, nature-related opportunities include activities that create positive outcomes for nature or mitigate negative impacts on nature.

The <u>TNFD Biotechnology and Pharmaceutical Sector</u> <u>Guidance</u> outlines both business performance opportunities as well as sustainability performance opportunities.

# Nature related opportunities associated with the pharmaceutical sector value chain

We have based <u>Table 3</u> on the TNFD Biotechnology and Pharmaceutical Sector Guidance<sup>46</sup>

The TNFD Sector Guidance provides a framework for identifying and managing nature-related risks and opportunities specific to the pharmaceutical sector.

In developing this Roadmap, we have used the TNFD sector guidance to help inform the pharmaceutical sector's nature-related opportunities. We have further refined this assessment through stakeholder consultations with industry peers to help develop examples specific to the pharmaceutical sector.

Business performance opportunity categories	Examples specific to the pharmaceutical sector								
		Examples specific to the pharmaceutical sector							
		Increased revenue coming from access to new mar							
Markets	Changing dynamics in overall markets	For example: Expanding into regions with rising dem green chemistry, biodegradable materials and energy consumers.							
		Additionally, companies investing in nature-based s mitigate environmental risks and enhance long-term							
		Increased productivity from switch to more efficien							
Resource efficiency	Transition to more efficient services and processes that require fewer natural resources, energy or impacts on nature	For example: Adopting solvent-free or water-based solvents that companies would otherwise need to a less heat or harsh conditions to process, as water of efficient, eco-friendly production while cutting cost offs of increased water use in these processes. Tran balanced decision-making.							
		Increased financial flows through agreements with green finance							
	Access to capital markets or financing connected to positive nature impacts	For example: Companies can secure green finance like reducing carbon footprints or implementing ec sustainability-linked loans, which incentivize nature lower-cost financing for projects that contribute to							
		Increased revenue due to R&D and new materials/p fermentation-based sources)							
	Creation or delivery of less natural resource- intensive products and services	For example: Pioneering the development of plant-b solvents and meets increasing consumer and regula brand reputation and attract investors and custom							
		Increase in talent attraction and retention and incre							
Rennational Canital	Changes in perception concerning a company's nature impacts	For example: A strong commitment to nature-pos loyalty. This improved public perception can resul engaged and motivated workforce.							
Sustainability performance opportunity categories	Examples specific to the pharmaceutical sector								
Sustainable use of natural resources	Sustainable sourcing and resource substitution	Certification schemes that ensure the sustainable h companies achieve increased market credibility and traditional plastics to bio-plastics.							
Ecosystem protection,	Direct restoration, conservation or protection of ecosystems	Positioning as a sustainability leader by investing plants and animals, can enhance the resilience of offering reputational benefits that may contribu							

#### Table 3: Nature-related opportunities associated with the pharmaceutical sector value chain

#### arkets and from process innovation

mand for sustainable healthcare solutions presents revenue potential, while process innovations like ergy-efficient manufacturing can reduce environmental impact and increase appeal to eco-conscious

solutions and resilient supply chains offer attractive opportunities for investors, as these initiatives rm business stability and market competitiveness.

ent manufacturing systems (e.g., green chemistry)

d formulations in pharmaceutical production reduces waste by eliminating or minimizing harmful dispose of or treat as hazardous waste. These processes also reduce energy consumption by requiring or solvent-free methods often operate at lower temperatures and pressures. This leads to more sts related to waste management and energy use. However, it is important to acknowledge the tradeansparency in understanding and managing such trade-offs is essential to ensure sustainable and

h banks and debt capital markets on sustainable finance frameworks to access new sources of

e through partnerships with banks and debt capital markets by committing to sustainable practices co-friendly production methods. These agreements often involve frameworks such as green bonds or re-positive initiatives, attract investors focused on environmental responsibility and provide access to co sustainability.

product innovation and discovery (e.g., pioneering the development of solvents derived from plant- or

-based or microbial-derived solvents offers a more sustainable alternative to traditional chemical Ilatory demand for eco-friendly products. These types of innovations can open new markets, enhance mers who prioritize sustainability.

crease in revenue/brand value thanks to high nature-related reputation

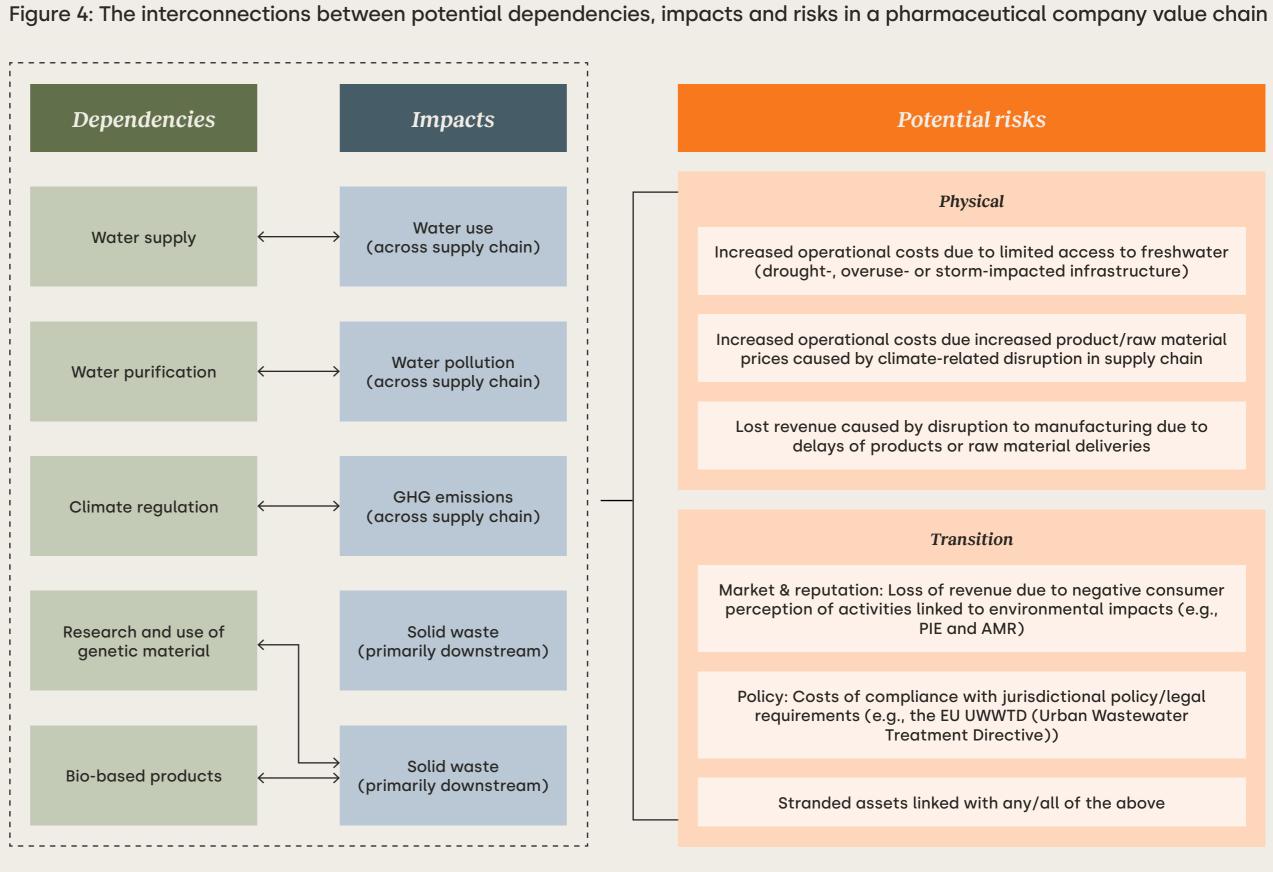
tive initiatives can enhance a company's reputation, boosting brand value and fostering customer in increased sales, partnerships and investor confidence, driving revenue growth alongside a more

harvesting of bio-based raw materials and the responsible cultivation of medicinal plants can help nd reputational status. This is also true for alternative sourcing strategies, such as transitioning from

in initiatives to conserve and restore areas important for biodiversity, particularly those rich in medicinal supply chains. This focus on long-term resource stability supports business continuity while also to increased market valuation.

#### The interconnections between potential dependencies, impacts and risks in a pharmaceutical company value chain

Figure 4 demonstrates some of the interrelationships between dependencies, impacts and risks that may be present in a pharmaceutical company's value chain. It should consider both impacts and dependencies when evaluating the nature-related risks and opportunities relevant to a business.





Risks can arise from dependencies and/or impacts

### Stage 2: Commit and Transform (targets for priority actions)

Prioritize further action based on risks and opportunities for the business and stakeholders.

Once companies have completed an initial materiality screening process, they should use material impacts and dependencies to inform the design of nature-related commitments, actions and targets.

Credible, realistic and impactful nature commitments (including associated targets) require a company to understand the actions it can take to address its priority dependencies, impacts, risks and opportunities on nature.

The foundational steps to "Commit and Transform" include:

- 1. Setting science-informed targets: Set time-bound, science-based, location-specific targets and linked metrics to track progress on reducing priority impact drivers on nature;
- 2. Taking priority actions: Identify the existing and additional priority actions needed to avoid and reduce negative impacts and promote opportunities to restore and regenerate;
- **3. Transforming the system:** Identify additional actions needed that transform business models and business activities to address barriers and improve the enabling environment (policy, financing, technology, infrastructure).

# SBTN Action Framework with examples of actions for the pharmaceutical sector

To fully understand and apply the SBTNs Action Framework, it is necessary to understand its structured approach to guiding businesses toward meaningful nature-positive outcomes. The framework provides an outline for the integration of nature-related priorities into business operations and strategy.

The SBTN's Action Framework (AR3T) provides a general framework for businesses to drive nature action and align with the mitigation hierarchy set out in the International Financial Corporation's Performance Standard 6. The order of this mitigation hierarchy generally aligns with the maturity of a business and therefore the types of actions possible for them to execute to drive nature-positive outcomes. For example, even organizations at a lower maturity can use early lessons learned to identify and avoid activities or suppliers that have a significant negative impact on nature. As they improve their knowledge base and the nuance of nature impact materiality, businesses can reduce the impact of their activities and in their value chain through alternative sourcing or process innovation. At an even higher maturity, businesses can start to pay attention to actions that directly remediate negative impacts on nature, such as restoration of the watersheds

where they have manufacturing sites. As these positive actions accumulate, nature-positive impacts can extend beyond the pharmaceutical value chain and result in transformative influence on wider ecosystems, communities and the economy.

The framework emphasizes understanding and addressing a company's impacts and dependencies on nature, as well as the associated risks and opportunities. Specifically, the SBTN framework enables businesses to:

- 1. Assess impacts: Identify how operations and supply chains affect ecosystems, biodiversity and natural resources. For the pharmaceutical sector, this includes considerations such as solid waste, water use and water pollution.
- 2. Understand dependencies: Recognize reliance on natural systems. For the pharmaceutical sector, this includes considerations such as water availability, stable climate and genetic or biological resource information.
- **3. Mitigate risks**: Address risks arising from nature loss, such as regulatory penalties from API pollution, supply chain disruptions, reputational damage and reduced resource availability.

#### **Stage 2.1 - Set science-informed targets**

Set time-bound, science-based, location-specific targets and linked metrics to track progress on reducing priority impact drivers on nature loss. Note that the second phase of this Roadmap will include details on metrics and target setting, specifically looking to establish key nature-positive metrics and indicators for this sector.

#### Why do this:

Companies should set science-based targets to help address the main drivers of nature loss across their value chains. In doing so, they align with rising global standards for environmental stewardship and enhance their accountability to clients, customers and stakeholders. Science-based targets act as crucial drivers of corporate action, influencing key functions such as R&D, material management and supply chain operations. Additionally, these targets can also help support businesses in meeting regulatory and legislative requirements, both locally and globally, as well as voluntary frameworks. Reporting on progress against widely accepted metrics and targets enables financial institutions and other stakeholders to hold companies accountable for their environmental impacts and better assess their performance and transitions plans. Establishing measurable, time-bound goals creates clear pathways for effective action, which can help manage reputational risks, especially as businesses must increasingly account for their contributions to nature loss. Science-based targets offer a structured approach to prioritizing actions that lead to nature-positive outcomes by halting or reversing harmful activities and driving sustainable practices.

#### What to do:

- $\rightarrow$  Consider the activities throughout the value chain that typically exacerbate key drivers of nature loss and the actions the company is already taking (or has planned to take) to avoid and reduce these negative impacts.
- $\rightarrow$  Analyze and prioritize the most material issues and locations for action. Consider the priority terrestrial and aquatic ecosystems in direct operations identified during the Assess stage to set ecosystem-specific baseline values for impact driver-related metrics.
- $\rightarrow$  Set science-based targets at various levels, including the impact driver level and the company response level, aligned with the metrics used to establish the baseline. Targets should reflect the company's position in the value chain and they should tailor them to address specific nature-related challenges. For companies with a direct nature footprint, this means prioritizing actions in operational locations where they can drive immediate impact. For companies further downstream with less direct influence, targets may focus on corporate and supply chain decisions, such as sustainable procurement policies, product design or business model innovation.
- $\rightarrow$  Build on what the company has done so far, set targets accordingly and disclose the methodology used.

SBTN defines science-based targets as "measurable, actionable and time-bound objectives, based on the best available science, which allow actors to align with Earth's limits and societal sustainability goals."

### Stage 2.2 - Take priority actions

The pharmaceutical sector has a key role to play in the transition to a nature-positive economy, particularly in connection with the priority impacts and dependencies on nature identified. Actors in the sector can reduce their negative nature-related impacts, protect nature and promote restoration by prioritizing the top five actions outlined in this Roadmap. In doing so, they can simultaneously mitigate operational risk, unlock commercial opportunities and realize co-benefits for society, people and health.

The actions outlined in this section are relevant across the pharmaceutical value chain and may require engagement with suppliers, customers and regulatory bodies. Advocacy plays a crucial role in championing sustainable change, ensuring that companies carry out efforts to deliver these priority actions and transform the sector in alignment with a just and equitable transition. This must include meaningful dialogue with affected groups, such as employees, local communities, Indigenous Peoples and marginalized communities.

While these actions provide a framework, sustainability practitioners must consider their company's specific context and maturity level to determine the most material actions to prioritize.

#### Why do this:

Companies need to take action to address the key impact drivers of nature loss. While many companies already have measures in place targeting some of these impact drivers, they may have not fully evaluated them against the materiality assessment.

#### What to do:

To effectively avoid and reduce negative impacts while promoting restoration and regeneration, companies should consider the following.

- $\rightarrow$  Map existing actions against the impact drivers prioritized through the materiality assessment and correct the course: understand what actions the company is already taking and should continue, which ones it can defer for long-term consideration and which new actions it needs to implement.
- $\rightarrow$  These actions should align with the emerging guidance for target-setting (refer to SBTN's guidance on Act, step 4) and tied to relevant and feasible metrics to measure progress and support reporting and accountability.
- $\rightarrow$  For all actions, systematically apply the principles of the action framework to avoid and reduce negative impacts, while maximizing positive contributions. This includes avoiding and **reducing** pressure on nature loss; regenerating and restoring ecosystems to enable nature's recovery; and transforming the underlying systems driving nature loss. This framework provides a holistic approach to effectively integrating nature considerations into corporate strategies (see Figure 5).

Focus on actions in the company's direct control, as well as actions in its areas of influence, including relationships with suppliers, CDMOs, customers and the broader landscapes in which they operate. Companies should consider actions across three main levels:

- 1. Corporate
- 2. Operations and priority value chains
- 3. Broader system change (see Stage 2.3: Transform the system)

In response to key impacts and dependencies caused by and affecting the pharmaceutical sector, companies can prioritize several key action areas to drive progress on nature positive. This is not a mandatory list of steps but a comprehensive set of actions that all pharmaceutical companies should aim to implement or promote in their direct operations and across their value chains.

They should consider all actions in the context of the strong regulatory environment in which the sector operates. To be successful, the companies will need to implement the actions in collaboration with key stakeholders, particularly regulators, to ensure compliance with all relevant legal and industry standards. Beyond compliance, companies should actively engage in advocacy to shape and advance regulatory frameworks that support innovation and sustainability. By proactively working with regulators and other stakeholders, the sector can meet current standards and influence the development of policies that address emerging challenges and support a more resilient and responsible industry.

Foundations for the pharmaceutical sector Stage 2.2 – Take priority actions

#### SBTN's Action Framework, with examples of actions

Figure 5 illustrates the SBTN Action Framework's four interconnected pillars of action, along with specific examples of initiatives that pharmaceutical companies can implement.

#### Figure 5: SBTN's Action Framework with examples of actions for the pharmaceutical sector

#### Restore and regenerate

- Restore habitat in and around manufacturing sites
- Protect and restore watersheds at the water basin level in regions linked to direct operations by supporting or funding local initiatives and projects

#### Reduce

- $\rightarrow$  Reduce water use during the manufacturing process through increased water efficiency and recycling
- $\rightarrow$  Reduce water and soil pollution risk from APIs, especially antibiotics, harmful chemicals and other relevant substances
- $\rightarrow$  Reduce manufacturing waste by improving the efficiency of material use and expanding the use of recycled or biodegradable materials, such as for medicine delivery devices
- → Work with stakeholders to establish circular economy principles across manufacturing and distribution
- $\rightarrow$  Reduce waste to landfill by introducing a waste hierarchy into management systems

### TRANSFORM

contribute to system-wide cha

#### **RESTORE &** REGENERATE

Recover the state of nature

#### REDUCE

When prevention is not possible, minimize impacts

#### **AVOID** Prevent impacts on nature entirely

Source: Adapted from WBCSD (2025). What does nature-positive mean for business?



- → Avoid ecosystem conversion, including deforestation in supply chains, especially related to the supply of bio-based materials
- $\rightarrow$  Avoid establishing new operations in/adjacent to areas that are important for biodiversity or sensitive locations (high conservation value, key biodiversity areas (KBAs), areas of high water stress)
- $\rightarrow$  Avoid and reduce the release of emissions in operations and land use (including GHG and other non-GHG air pollutants)

#### Transform

- → Achieve system-wide change through collaborative efforts across industries, governments and civil society
- For example, water, sanitation and hygiene (WASH) programs, which focus on improving access to safe water, adequate sanitation and hygiene practices, demonstrate how collective action can help address systemic challenges. Through promoting public health, well-being and sustainability, WASH initiatives highlight how collaborative approaches can amplify contributions that lead to meaningful, long-term impact.

#### Priority actions in the pharmaceutical sector

The top five priority action areas for pharmaceutical companies align with the AR3T steps of the SBTN Action Framework. This provides a focused approach to addressing the most critical nature-related challenges. These actions represent high-impact opportunities and serve as an entry point for companies aiming to integrate nature-positive practices into their operations.

For a broader perspective, <u>Annex 5.3</u> provides a comprehensive list of actions categorized by different phases of the value chain. Together, the top five priority actions and the comprehensive list provide a roadmap that balances short-term impact with long-term, systemwide transformation, enabling companies to tailor their strategies based on their unique value chain position and maturity in addressing nature-related issues.

Note that the next iteration of the Roadmaps will focus on establishing key nature-positive metrics and indicators for the sector.

#### Top five priority actions

1. Reduce water use across the value chain by establishing sustainable water management practices and contribute to restoring and replenishing watersheds

Reduce manufacturing water use through improved efficiency during product development, recycling water, closed-loop systems and altering hard infrastructure, such as insulating cooling towers for reaction chambers (consider potential trade-offs relating to energy consumption). Increase understanding of dependencies on water supply across the value chain and prioritize mitigation in areas of high-water stress or drought risk. Take a basin-level approach to water management,

#### Figure 6: Top five priority actions in the pharmaceutical sector



reducing the strain on local water resources that communities and ecosystems rely on and ensuring sustainable freshwater withdrawal.

Enhance traceability and engage with suppliers and CDMOs across the value chain to understand their water risks and increase water-use efficiency. thereby minimizing water stress impacts. Participate in river basin restoration and replenishment activities, prioritizing nature-based solutions (NbS) - working with governments, NGOs and local communities where appropriate. For long-term water sourcing, locate resources near manufacturing sites while considering societal, climate and biodiversity impacts. Engage with local communities, hydrologists and other stakeholders, especially in water-stressed regions and areas critical

#### Action 3 Action 4 Action 5 Avoid and reduce Source responsibly, Reduce solid waste the release of GHG improve supply chain across the value chain by optimizing product emissions across the traceability and entire value chain transparency and and process design, accelerate the use adopting innovative of alternative lower manufacturing and impact materials circular business models, and promoting circularity among regulators, policymakers and customers

Transform the system to support these objectives

for biodiversity, to ensure sustainable and responsible water use.

Improvements in water-use efficiency would serve to mitigate the risks of water stress, flooding and drought on ecosystems and the human communities that rely upon them. By increasing the availability of surface and groundwater resources, healthier and more resilient soilstabilizing flora can thrive, providing flood protection and reduced runoff during precipitation events. If the sector managed water resources in a more sustainable manner, local communities may be able to reap the benefits of a more reliable water supply, even during periods of low precipitation.

UNESCO's World Water Assessment Programme describes a basin-level approach as an approach defined by geographical and hydrological characteristics that "facilitates the practical integration of downstream and upstream as well as basin-wide issues and the incorporation of quantity and quality aspects of the basin's available surface and groundwater resources."

2. Reduce pollution risk from APIs – especially antibiotics, harmful chemicals and other relevant substances through product innovation, industry-level collaboration and education programs

Minimize the release of APIs, chemicals and other substances from pharmaceutical manufacturing processes and meet and exceed requirements and regulations for specific production sites wherever possible. Incorporate environmental considerations into pharmaceutical R&D, including the persistence, mobility, bioaccumulation and ecotoxicity of APIs, to advance the development of greener, benign-by-design APIs while accounting for the lead time needed for research, development and testing before patient availability.49 Mitigate the environmental impacts of antibiotics released into wastewater discharge by certifying according to standards, such as the British Standards Institute (BSI) Antibiotic Manufacturing Standard.

Work collaboratively to identify the most material effluents from manufacturing processes, based on their ecotoxicity and how commonly the sector uses them. Share end-of-life solutions with users through educational campaigns on responsible product use and disposal, as a significant portion of the impact from APIs and antibiotics

often occurs downstream in the value chain, such as during product use and disposal.<sup>50</sup> Take-back schemes for used devices, primary packaging and unused medicines offer a valuable opportunity to enhance circularity, reduce water pollution and mitigate environmental impacts. Additionally, working collaboratively with regional and municipal wastewater treatment plants ensures that their systems can adequately support the removal of ecotoxic chemicals and their decomposition techniques can mitigate downstream accumulation.

For chemicals that are not APIs or antibiotics, transition to circular models in the sourcing of reagents, solvents, buffers and other feedstocks, as well as in the design and manufacturing of products. Implement downstream solutions in the value chain for chemicals and by-products where feasible, while mitigating negative impacts through product and process design, site risk assessments and end-of-life management strategies. These efforts aim to reduce ecotoxic and nutrient pollution, contributing to lower risks of acute and chronic health impacts in humans and wildlife, such as oxidative stress, carcinogenicity and reproductive toxicity.

Foundations for the pharmaceutical sector Stage 2.2 - Take priority actions

Additionally, address the advancement of AMR in the environment by prioritizing measures to mitigate antibiotic pollution. This includes actions such as implementing robust waste management systems and ensuring responsible antibiotic use along with storage, disposal and treatment practices. These types of actions are critical to reducing the risk of drug-resistant disease outbreaks, safeguarding public health and preserving ecosystem resilience to biological and environmental stressors.

# 3. Avoid and reduce the release of GHG emissions across the entire value chain

Establish a <u>science-based emissions reduction target</u> and encourage suppliers and CDMOs to follow suit. Use product-level life-cycle assessment (LCA) data to identify priority areas and actions to minimize GHG emissions, thereby reducing the sector's contribution to climate change and its impact on nature. Engage with suppliers and CDMOs on energy use and efficiency, promoting the adoption of clean, renewable energy sources.

Increase the efficiency of processes related to the manufacturing, storage and distribution of products.

Increase the efficiency of manufacturing processes, for example by adopting green chemistry principles, as well as the efficiency of production, storage and distribution facilities and processes. In particular, focus on equipment with significant energy and heat demand, such as heating, ventilation and air conditioning (HVAC) and purified water systems.<sup>51</sup> Consider opportunities for emissions reductions related to the manufacturing, storage and distribution of products, such as energy-efficient cooling and refrigeration systems, to reduce patient travel to access pharmaceutical products.

By contributing to global net-zero goals, the pharmaceutical sector can be part of efforts that mitigate the future frequency and severity of natural disasters, protecting ecological stability and livelihoods.

The sector should also consider trade-offs, such as the land-use impacts of expanded renewable energy generation infrastructure, in decision-making.

#### 4. Source responsibly, improve supply chain traceability and transparency and accelerate the use of alternative, lower impact materials

Identify the key chemical and agricultural inputs used and understand their natural source. Perform this work



individually or in collaboration with the Pharmaceutical Environment Group (PEG) or the Pharmaceutical Supply Chain Initiative (PSCI). Assess the environmental impacts and risks associated with key commodities used in production processes, such as palm oil or petrochemicals, supported by pharmaceutical product LCAs, the SBTN High Impact Commodity (HIC) list<sup>52</sup> and other tools to locate these impacts and risks in the value chain.

Engage with suppliers and CDMOs to enhance their sustainability performance and product traceability by establishing clear standards (including certification) on climate and nature, while providing support to accelerate improvements where needed. Improve traceability to identify and mitigate impacts through end-to-end supply chains by identifying data gaps in product or ingredient traceability from tier 1 suppliers, ideally down to the raw material level for the most mature companies. Ensure the inclusion of social and human rights considerations for local communities in the standards.

Accelerate the use of alternative, lower-impact materials where possible and work collaboratively with the industry and regulators (such as the US Food and Drug Administration (FDA) and the EU European Medicines Agency (EMA)) to ensure acceptance and enable a timely transition. For instance, transitioning to synthetic LAL for pharmaceutical product testing would require a productby-product filing process unless regulators identify and approve an alternative approach. Consider potential trade-offs relating to alternative materials.

Undertaking such interventions can benefit nature by mitigating the risk of unsustainable resource extraction and benefit society by championing human rights across the pharmaceutical value chain and boosting the resilience of the value chain to supply shocks, protecting economies and social cohesion in the process.

5. Reduce solid waste across the value chain by optimizing product and process design, adopting innovative manufacturing and circular business models and promoting circularity among regulators, policymakers and customers

Collaborate with actors across the value chain to design out waste and reduce solid waste generation. Engage with current suppliers, CDMOs and other stakeholders to promote circularity and adopt waste hierarchies in management systems across the value chain. Enhance material efficiency by implementing innovative practices and technologies, such as maximizing yield, adopting continuous manufacturing techniques and redesigning product systems to minimize waste across all stages of production, delivery and consumption.

Review current product designs to identify opportunities for reducing overall material use and increasing the incorporation of recycled materials, moving away from virgin plastics and paper. Work closely with policymakers, supporting policies that reinforce circularity and reduce waste, such as collective waste gathering and alternative sustainable device and component materials.

Reduce the downstream impacts of product use through education campaigns on responsible product use and disposal, including appropriate handling of unused or expired medicines.

Additionally, design pharmaceutical products, devices and components to maximize circularity. Collaborate across industries to align on standard recyclable component and device formats, driving economies of scale, supporting the global development of appropriate recycling infrastructure and maximizing material recovery. Work with organizations and legislators developing recyclability guidance to ensure comprehensive guidelines exist for all design formats. Engage with regulators to facilitate a timely transition and strive to close the loop wherever feasible.

Recyclability guidance typically emphasizes the curbside recycling of materials but it is also essential to address pharmaceutical and industrial hygiene risks. Establishing industry-wide take-back schemes for used devices can enhance economies of scale while simplifying the return process for patients.

#### Summary of priority actions

Many of the actions are relevant across the pharmaceutical value chain and require engagement with suppliers, customers or regulatory bodies. In particular, advocacy for enabling policies at local, regional, national and global levels plays a crucial role in championing sustainable change and transforming entire sectors. Importantly, the actors delivering these priority actions and transforming the sector must do so in alignment with a just and equitable transition, including meaningful dialogue with affected groups, such as employees, local communities, Indigenous Peoples and marginalized communities. Many actors in the sector have already committed to aligning with TNFD disclosures and are integrating the LEAP approach into their strategy development and execution.

#### Stage 2.3 - Transform the system

#### Identify further actions to transform the system.

#### Why do this:

The nature- and climate-related challenges confronting businesses and society are complex and interconnected and involve a wide range of stakeholders. Individual company actions are important and will likely form the first steps in the transition towards nature positive. Driving the transformation needed to reach a nature-positive global economy will require the collective actions of sector and industry stakeholders with influence beyond an individual company's sphere of control. Companies should therefore explore ways to drive enduring systemic change both in and beyond their value chains, addressing the root causes of nature loss while simultaneously driving positive climate change and social inequality impacts.

In Phase II of the Roadmap, we will tie the actions (in section 5.3 Full table of actions) identified in this Foundational Roadmap to a set of metrics to measure and report on their impacts over time. This will enable more targeted, transformative actions by guiding sustainability practitioners in prioritizing metrics that track and disclose efforts to address their most material nature impacts and dependencies, in alignment with key voluntary and regulatory frameworks. For further information on Phase II, refer to Section 4.

#### What to do:

- $\rightarrow\,$  Consider the key enablers needed to accelerate and scale up action, such as supportive government policies, adequate financing and access to technology.
- $\rightarrow$  Consider trade-offs, such as supply challenges, when transitioning to regeneratively farmed pharmaceutical crops and identify collaborative actions to address these issues.
- $\rightarrow$  Identify the roles and responsibilities required to overcome systemic barriers and develop a plan to engage with relevant stakeholders, including industry peers, suppliers, CDMOs and operational teams.
- → Advocate for a supportive enabling environment, such as publicly demonstrating support for key policies and financing for infrastructure, institutions and technology.
- → Establish sector-wide commitments to voluntary frameworks that focus on driving nature-positive outcomes, such as the TNFD.
- $\rightarrow$  Engage with sectors upstream in the value chain (such as the chemical or agricultural sectors) to align priorities and responsibilities for influence and impact.

When selecting priority actions in line with the recommendations from <u>Stage 2.2</u> and the comprehensive list of actions in <u>Annex 5.3</u>, it is important to ensure that these are long-lasting and transformative.

It is only possible to achieve transformative action through significant changes in business operations, technology, advocacy and business models and value chains.

The identified priority actions are transformative when implemented at scale, both in the company and across the entire pharmaceutical sector.



Transformative action requires collaboration at the system or ecosystem level and across the entire value chain. For example, a pharmaceutical company might introduce innovations such as biodegradable drug formulations or advanced water treatment systems for APIs, contributing towards the reduction of environmental pressures. When adopted by other industry members, these innovations can drive system-wide transformative change. To achieve nature-positive outcomes at an ecosystem level, cooperation among all stakeholders is essential.

Moving from priority actions to transformative actions requires an advanced level of maturity. At this stage, a company understands its value chain and can identify partners and stakeholders to collaborate with to maximize impact. We outline maturity levels in the <u>Roadmaps to</u> <u>Nature Positive: Foundations for all businesses</u>. They partially correspond to the levels of action in SBTN's mitigation hierarchy.

#### Table 4: The different levels of maturity for transformative action

Maturity level	Transformative act
Starting	Focus on ad hoc actions
Developing	Focus on ad hoc actions priority actions.
Advancing	The prioritization of strat multiple core benefits; and and leading companies of can verify that they have
Leading	The company prioritizes trade-offs between climo key locations.

#### tion

that aim to halt (avoid and reduce) or reverse (restore or regenerate) nature loss; advocacy is limited.

that consider both halting and reversing nature loss; advocacy is visible but does not align with

tegic actions takes place according to where the company has the most influence or impact and the dvocacy somewhat aligns with priority actions and partially considers local stakeholders. Advanced also continuously improve their nature-related data collection, processing and management, so they e covered priority actions.

strategic actions according to where it has the most influence and impact; this considers links and ate, nature and equity; advocacy fully aligns with priority actions and focuses on local stakeholders in

#### → Stage 3: Disclose (initial disclosures)

Nature-related disclosures help companies communicate how they are considering nature in their value chains and how they are taking action towards nature-positive outcomes. Disclosure will directly contribute to the achievement of GBF Target 15. Both voluntary and mandatory accountability mechanisms increasingly require them.

#### Why do this:

Expectations are growing for companies to monitor and publicly report on their progress and be transparent on the steps taken to advance on their nature journey. For certain topics, especially when material to the business, companies must disclose this information in accordance with mandatory frameworks like the nature-related ESRS standards in the CSRD. On the other hand, for topics that are less material, companies may opt for voluntary disclosures, such as those guided by the TNFD Framework. By disclosing nature-related information systematically, companies provide investors and wider society with the transparency needed to make informed decisions about the comparative sustainability performance of companies and sectors.

In the context of the CSRD, companies must assess both the financial materiality and the impact of their operations on nature, a concept known as double materiality. This means that companies must evaluate how nature-related risks and opportunities affect their financial performance and disclose how their operations and value chains impact nature and biodiversity. This dual perspective is crucial to fully understanding and reporting on a company's sustainability performance.

Investors will evaluate whether a company is creating additional enterprise value through its management of nature-related risks and opportunities. They will also consider the collective actions of companies to address systemic risks. Other stakeholders may focus on the total impact of a company or sector from the perspective of a social license to operate, including its alignment with societal goals for nature. Disclosures therefore provide an opportunity for a company to highlight its nature-related strategy, the progress made in its delivery and the value it creates.

#### What to do:

- $\rightarrow$  Follow regulated nature reporting requirements as the foundation for nature disclosures if it is in the company's scope.
- $\rightarrow$  Aside from or in addition to regulated disclosures, the TNFD recommendations provide a strong basis and clear guidance for nature risk management and reporting.
- $\rightarrow$  Initial disclosures can include the methodologies and outputs of a company's materiality assessment, value chain mapping, target-setting and descriptions of actions

the company will undertake to make progress on targets and deliver system change. As a company's nature journey matures, disclosure ambitions and granularity can increase.

#### $\rightarrow$ The foundational steps to "Disclose" include:

- Leveraging existing disclosures that are relevant to nature, such as those related to water, deforestation and other environmental impacts;
- Reporting on the foundational "Assess" and "Commit and Transform" stages (methodologies and outputs).

In the dynamic nature space, businesses may risk exposure to accusations of greenwashing on the one hand or socalled green "hushing" (understating commitments and progress for fear of greenwashing backlash) on the other. Focusing on the most material dependencies, impacts, risks and opportunities, as outlined in this document and following widely accepted disclosure frameworks such as TNFD will help ensure a credible approach.

# 04. Next steps for the Roadmaps to Nature Positive

# 04. Next steps for the Roadmaps to Nature Positive

Achieving the collective goal of halting and reversing nature loss by 2030, with full recovery by 2050 as outlined in the Global Biodiversity Framework, demands more than individual company efforts; it requires system-level transformations. We have designed our **<u>Roadmaps to Nature Positive</u>** to drive such transformations, bringing together peers from the same sectors or economic systems to develop a shared agenda to accelerate nature-positive ambitions, actions and accountability. Other initiatives in the pharmaceutical sector, such as the Pharmaceutical Supply Chain Initiative and the Pharmaceutical Environmental Group, also contribute to driving sectorwide transformation in company operations as well as supporting positive ripple effects throughout the value chain. These targeted efforts provide companies with tailored guidance, enabling them to align with industry standards and collaborate effectively with industry peers to drive collective progress toward nature-positive outcomes.

As part of Phase II of the Roadmaps, the actions (in section **5.3 Full table of actions**) identified in this Foundational Roadmap will tie to a set of metrics to measure and report on their impacts over time. These Roadmaps prioritize metrics based on an evaluation against different criteria, including their alignment with key voluntary and regulatory frameworks, such as the TNFD and the CSRD. The outcomes of this initiative will be accessible via a user-friendly Nature Metrics Portal (the Portal), with an initial version we aim to launch at the United Nations Climate Change Conference (COP30) in November 2025. The widespread adoption of the metrics prioritized in the portal will foster the harmonization of the nature-related metrics used by businesses, leading to an acceleration of corporate action and accountability on nature. This harmonization will also facilitate comparisons across companies using similar datasets, helping to direct financial flows toward solutions that make the greatest progress towards nature positive.

**Disclaimer:** We intend for the Roadmaps to Nature Positive, encompassing both Phase I and Phase II, to be guidelines to assist companies in the sector rather than as a mandatory framework or binding commitments. We encourage companies and organizations to use the Roadmaps as a resource to facilitate progress on nature-positive outcomes at both the business and sector-wide levels.

# 05. Annexes



### Annexes

#### Methodology and business activity groupings for impact and dependency tables

We used the July 2024 update of ENCORE to map the generic impacts and dependencies associated with the pharmaceutical sector value chain. We aligned the ISIC-coded business activities from the ENCORE knowledge database with the value chain components described in Figure 3: Scope of the value chain for the pharmaceutical sector. We then refined this mapping through consultation with members of the WBCSD Roadmap to Nature Positive for the Pharmaceutical Sector working group.

Table 5: Mapping pharmaceutical value of business activities

Value chain component	ISIC-aligned busin Exposure (ENCORI
Agricultural products	Raising of cattle and bu growing of other non-pe plant propagation
Chemicals	Manufacturing of basic chemical products, mar
Materials	Manufacturing of fertiliz mining of iron ores, mini
Energy	Fossil fuel energy produ fuels through mains, ext
Pharmaceutical manufacturing and services	Manufacturing of pharm experimental developm
Healthcare	Hospital activities, med
Waste management	Material recovery, reme
Water utilities	Sewerage, waste treatm
Transport and distribution	Freight air transport, inl warehousing and storag

#### Table 5: Mapping pharmaceutical value chain components to International Standard Industrial Classification (ISIC)

#### ess activities selected in the Exploring Natural Capital Opportunities, Risks and E) database

uffaloes, growing of cereals (except rice), leguminous crops and oil seeds, growing of fiber crops, erennial crops, aquaculture, gathering of non-wood forest products, growing of perennial crops, logging,

chemicals, manufacturing of plastics and synthetic rubber in primary forms, manufacturing of other nufacturing of refined petroleum products

izers and nitrogen compounds, manufacturing of plastics products, manufacturing of rubber products, ing of non-ferrous metal ores, manufacturing of paper and paper products

uction, solar energy production, wind energy production, manufacturing of gas, distribution of gaseous traction of crude petroleum, extraction of natural gas

maceuticals, medicinal chemical and botanical products, activities of head offices, research and nent using natural sciences and engineering

lical and dental practice activities

ediation activities and other waste management services, waste collection

ment and disposal, water collection, treatment and supply

land water transport, other land transport, sea and coastal water transport, transport via railways, ge

#### Full risk & opportunity matrix

This table provides examples of risks and opportunities for the pharmaceutical sector, disaggregated based on the Taskforce on Nature-related Financial Disclosures (TNFD) risks and opportunities (R&O) taxonomy. The purpose of the table is to provide readers with a foundation of understanding from which to build their own list of risks and opportunities specific to their operations and value chain. These examples are indicative but not exhaustive. Risks and opportunities will vary between companies depending on materiality. We have categorized each entry in the table by risk/ opportunity type in the top rows and stage of value chain in the left column. Each example risk/opportunity entry is independent of the others.



#### Table 6: Risk and opportunity matrix for the pharmaceutical value chain

Risks				Opportunities		
Physical		Transition				
Acute	Chronic	Markets and reputational	Policy and legal	Business performance	Sustainability performance	
Reduced revenue due to delay in production & operations from agricultural or forestry-related pharmaceutical manufacturing feedstock loss due to extreme weather events	Increased operating costs due to loss or reduction of water supply from increasing frequency & intensity of water scarcity	Reduced revenue due to downstream reputational/ market risk, (e.g., negative public perception of deforestation and pollution by suppliers & contract development & manufacturing organizations (CDMOs)	Reduced revenue from missed business opportunities	Reduced costs of supplier products due to more favorable agricultural & production conditions from improved ecosystem services		
Reduced revenue due to delay in production & operations from impeded supply of raw materials/ finished products caused by disruption of transportation routes by extreme weather events	Reduced revenue resulting from loss or disruption to supply of key pharmaceutical ingredients (e.g. bio- based materials) due to nature loss (e.g., squalene from shark liver due to lack of adoption of biosynthetic alternatives)	Increased costs from reduced supply & increased cost of commodities due to sustainable supply chain policies and commitments (e.g., deforestation- & conversion-free (DCF) & "land-sparing")	& supply chain disruption due to trade restrictions on materials sourced from nature-destructive practices	Reduced costs associated with innovative circular economy-compatible proc & product design		
Reduced revenue due to interrupted freshwater supplies caused by extreme weather & pollution events	Increased operating expense (OpEx) due to challenges in material sourcing (e.g., plant-based compounds, minerals) due to scarcity caused by shifts in climate patterns, over exploitation & habitat degradation	Increased cost of switching to sustainably sourced natural materials in response to shifting consumer preferences towards deforestation-free products		Increased supply chain resilience through supplier adoption of regenerative agriculture practices		
				Increased supply chain resilience through supplier adopt agriculture practices	ion of regenerative	
Reduced revenue due to interrupted freshwater supplies caused by extreme weather & pollution events	Increased operating expense (OpEx) due to challenges in material sourcing (e.g., plant-based compounds, minerals) due to scarcity caused by shifts in climate patterns, over exploitation & habitat	Increased cost of switching to sustainably sourced natural materials in response to shifting consumer preferences towards deforestation-free products	Increased due diligence & reporting costs (e.g., headcount, data collection and analysis) to comply with nature-related disclosure frameworks, such as land-use or deforestation regulation compliance	Increased revenue from improved public perception, therefore user confidence and purchasing appetite, due to community engagement in restoration activities (e.g., wetland restoration)		
	degradation		(relevant to all stages of the value chain)	Increased revenue from access to new markets due to increased user demand for innovative sustainable products		
				Reduced costs linked to fines and imposed remediation from pollution activities from investment in on-site waste management processes and infrastructure		
	Increased operating costs from climate-related	Reduced revenue or reduced access to markets from negative user perception of activities linked to environmental impacts (e.g., pharmaceuticals in the	Increased costs of jurisdictional penalties/ litigation for activities linked to negative environmental impacts (e.g., historic pollution from manufacturing sites)	Reduced OpEx spent on the maintenance of manufacturing and corporate sites due to climate- resilient, nature-based solution linked retrofits and construction		
		environment (PIE) and antimicrobial resistance (AMR)		Reduced OpEx and increased productivity from adopting more water- / energy- / resource-efficient technology and processes	-	
Reduced revenue & repair costs from increased			Increased costs of compliance with jurisdictional policy/legal requirements (e.g., the EU UWWTD (Urban Wastewater Treatment Directive)), which	Increased revenue/brand value due to improved public perception of company from nature-positive activities & products that can credibly demonstrate their environmental sustainability.		
frequency/intensity of storm damage to production sites & transportation infrastructure	impacts (i.e., higher industrial cooling costs under increasing temperatures)		requires waste treatment investment or other measures to combat environmental releases of active pharmaceutical ingredients (APIs) post-patient use	Improved talent attraction & retention due to positive employee sentiments towards a company's nature- positive activities & sustainability reputation		
	Increased operating costs & reduced productivity due to polluted water & air at production sites	Reduced demand, therefore revenue, for products due		Increased demand for new & existing products & services due to changing global health trends caused by climate change & nature loss		
		to global health trends impacted by climate change and nature loss	Reduced revenue due to the prohibition of access to genetic resources for R&D purposes	Increased credibility from market & reputational status through use of certificati schemes to ensure the sustainable harvesting of raw materials & sustainable cultivation of medicinal plants		
				Increased finance flows through access to new sources of green finance through products such as green bonds or sustainability-linked loans, lowering capital costs of nature-positive projects (e.g., nature-based remediation of land within production sites)		
	Increased costs of R&D & reduced revenue as AMR leads to reduced efficacy of product lines over time, requiring the development of new product lines & reduced demand for current product lines	Reduced revenue as a result of reputational damage following negative media coverage of API releases	Increased costs of compliance with jurisdictional policy/legal requirements (e.g., the EU UWWTD (Urban Wastewater Treatment Directive)), such as	Reduced costs linked to fines and imposed remediation from pollution activities from investment in downstream waste management processes and infrastructure		
	Increased costs of managing disruptions to key ecosystem services negatively affected by the downstream release of pharmaceuticals, APIs & other harmful substances	causing harm to biodiversity	waste treatment investment, or measures to combat environmental releases of APIs post-consumer use	Improved public perception and consumer confidence due to education campaigns for sustainable product end-of-life solutions and behaviors		

#### Full table of actions

This table lists an extensive, yet non-exhaustive, list of nature-positive actions that actors in the pharmaceutical value chain can take, disaggregated by stage of the value chain: upstream, direct operations and downstream. These actions expand on the priority actions outlined in <u>Section 2.2</u> of this Roadmap. We have mapped each action against an Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services (IPBES) driver of nature change and the Science Based Targets Network (SBTN) Action Framework mitigation hierarchy category. We have also attached illustrative trade-offs and barriers to each action. These additions are preliminary and subject to development in the next phase of these Roadmaps.

> → Companies should select the full set of actions based on the material impacts and dependencies specific to each company and then expanded as necessary.



Table 7: Risk and opportunity matrix for the pharmaceutical value chain

			SBTN Action Framework (AR3T)							
			resource use and	change	Pollution		Avoid	Reduce	Restore/ regenerate	Trade-offs & barriers
	Avoid conversion of natural land and ecosystems in supply chain, especially related to the supply of agricultural-, forestry-, or bio-based pharmaceutical manufacturing feedstocks. Achieve this by setting a no conversion of natural ecosystems target in supply chains and obtaining correct certifications from suppliers for key agricultural inputs.*t	x	x				x	x		Traceability and monitoring, reporting and verification (MRV) challenges; potential for negative impact on producer livelihoods; increased costs from greater full-time equivalent resources for due diligence.
	Reduce GHG emissions and their related climate change impacts on nature in the supply chain by encouraging suppliers and contract development and manufacturing organizations (CDMOs) to implement transparent climate strategies and targets, with clear actions to reduce their GHG emissions (prioritizing natural climate solutions (NCS)).*†			x				x		Requires significant funding, employee time & multi-stakeholder collaboration; some decarbonization levers might negatively impact nature, e.g., if they require land-use change.
Upstream	Reduce the use of fossil-based, non-renewable resources by switching to renewable, recycled or bio-based materials, where switching does not create additional impacts on nature, as well as supporting circular economy systems and solutions through supplier engagement.t		x	х				x		Lack of available alternatives; increased cost of alternatives; regulatory barriers to the acceptance of alternatives; potential for increased land use and water use to grow crops to make bio-based alternatives.
Upst	Restore degraded or converted ecosystems in the supply chain through engagement with suppliers and CDMOs to implement and promote landscape restoration or regeneration in and around their new/existing operations site.†	х	x						x	Requires significant project funding & multi-stakeholder collaboration (Indigenous Peoples and local communities (IPLC) engagement & free, prior and informed consent FPIC)); climate & nature values may differ; attribution & MRV challenges; outcomes may take years to materialize.
	Reduce air, water and soil pollution (including non-GHG emissions) from agriculture-related pharmaceutical manufacturing feedstocks by engaging with suppliers and encouraging the adoption of less polluting methods in alignment with a Science Based Targets Network (SBTN) Landscape Engagement Target.*				x			х		Reduced yields due to crop damage; potential for negative impact on producer livelihoods; stakeholder engagement difficulties due to complicated supply chains.
	Reduce upstream water use/consumption by engaging with suppliers and encouraging the adoption of more water-efficient processes.*t	х	x					х		Stakeholder engagement difficulties due to complex supply chains; Requires significant capex & OpEx to optimize or upgrade infrastructure and processes.
	Restore and protect watersheds at the water catchment level across the supply chain by supporting or funding local initiatives and projects.†								х	Requires significant project funding & multi-stakeholder collaboration (IPLC engagement & FPIC); climate & nature values may differ; attribution & MRV challenges; outcomes may take years to materialize.
	Carefully consider nature-related impacts, dependencies, risks and opportunities when establishing new operations, taking water risks and proximity to areas of significant biodiversity value into account. Embed biodiversity and water risk assessment criteria into the decision-making process when selecting new sites or expansions and prioritize action according to conservation hierarchy in locations that meet the criteria.*1	x					x			Regional constraints on expanding operations.
	Reduce water use in the manufacturing process through water efficiency and recycling.*†	x	x					х		Requires significant capital expenditure (CapEx) & OpEx to optimize or upgrade infrastructure and processes; potentially increased energy consumption of new/upgraded systems.
s	Reduce the release of non-GHG air pollutants from waste air through interventions including, but not limited to, enhanced air filtration systems or production step efficiency measures.*			х	х			х		Requires significant CapEx & OpEx to optimize or upgrade infrastructure and processes.
ations	Restore/conserve natural ecosystems in and around manufacturing sites, informed by local ecological expertise, community knowledge and best available data.*	х			х				x	Requires significant project funding & multi-stakeholder collaboration IPLC engagement & FPIC); climate & nature values may differ; attribution & MRV challenges; outcomes may take years to materialize.
opera	Reduce manufacturing waste by improving efficiency of material use and expanding use of recycled or biodegradable materials, such as for medicine delivery devices.*		Y	Y				v		Requires expenditure to conduct R&D, then optimize or upgrade infrastructure and processes; regulatory
Direct	Reduce manufacturing waste by designing processes and products to circular principles. Note that companies should only use biodegradable materials in specific circumstances, aligning with UN/EU guidance as this inhibits transition to a circular economy and can pollute recovery streams.*		X	X				*		barriers to changes in manufacturing process or use of recycled materials.
Ι	Reduce GHG emissions from sites and across the organization by progressing in line with a transparent climate strategy and science-based targets (prioritizing natural climate solutions (NCS))*			х				x		Requires expenditure to execute decarbonization levers; some decarbonization levers might potentially negatively impact nature.
	Reduce water and soil pollution risk from APIs, especially antibiotics, harmful chemicals and other relevant substances from manufacturing sites.*				х	х		х		Requires expenditure to optimize or upgrade infrastructure and processes; attribution & MRV challenges.
	Reduce waste to landfill by introducing a waste hierarchy into management systems.*				х			х		Downstream traceability and MRV challenges.
	Restore and protect watersheds at the water basin-level in regions linked to direct operations by supporting or funding local initiatives and projects.t	х							x	Requires significant project funding & multi-stakeholder collaboration (IPLC engagement & FPIC); climate & nature values may differ; attribution & MRV challenges; outcomes may take years to materialize.
	Reduce APIs (including antibiotics) in the environment by designing more biodegradable pharmaceuticals that decompose faster in the environment after excretion.*1				х			х		Requires significant project funding & multi-stakeholder collaboration; CapEx from R&D needed to reformulate products; regulatory barriers to the acceptance of alternatives; reduced drug efficacy after design change.
am and Flife	Reduce APIs (including antibiotics) in the environment through public education and information campaigns encouraging correct medicine disposal.*†				х			х		Requires expenditure to design and deliver education campaigns and to monitor positive impacts of campaigns; minimal control of end-user waste disposal behaviors.
rean of-lif	Reduce solid waste generated from the disposal of used pharmaceutical products through public education and information campaigns encouraging correct packaging & device disposal.*				х			х		Downstream traceability and MRV challenges; minimal control of end-user waste disposal behaviors.
nst. nd-	Reduce GHG emissions in products.*			х				х		Increased cost of alternative materials, CapEx from R&D needed to reformulate products.
Downst	Reduce use of single-use plastic in products where possible & design for packaging and devices to be recyclable.*			х	х			х		Increased cost of alternative materials, regulatory barriers to approved use of alternative materials or designs.
	Reduce APIs (including antibiotics) in the environment by investing in and supporting the development of technologies that enhance the removal of pharmaceutical residues from wastewater.*				x			x		Requires significant project funding & multi-stakeholder collaboration, CapEx from R&D needed to develop technologies.

\* The action relates to an identified "top 5" impact

† The action relates to an identified "top 5" dependency

#### Methodology and selection criteria for top 5 actions

We presented our Pharmaceutical Roadmap members with a long list of actions developed through the analysis of preceding Roadmaps to Nature Positive, sustainability reports and publications from the pharmaceutical sector and guidance from organizations such as the Taskforce on Nature-related Financial Disclosures (TNFD) and Science Based Targets Network (SBTN). Each member scored each action across each value chain component (upstream, direct operations and downstream) against the following selection criteria:

- $\rightarrow$  The extent to which the action would address the top impacts and dependencies outlined in this roadmap.
- $\rightarrow$  The degree of influence the pharmaceutical sector has on the realization of the action.
- $\rightarrow$  The overall level of positive effect the action would have on the environment and society.
- $\rightarrow$  We then consolidated these scores across value chain components and grouped them where necessary to produce the top 5 actions outlined in the main body of the Roadmap.

#### **Further reading**

The following guidance and tools are currently available to companies in the pharmaceutical sector:

- → The Nature Strategy Handbook (Business for Nature, 2023)
- → Additional sector guidance Biotechnology and pharmaceuticals (Taskforce on Nature-related Financial Disclosures (TNFD), 2024)
- → Roadmaps to Nature Positive: Foundations for all businesses (WBCSD, 2023)
- → <u>Accountability Framework</u> (Accountability Framework Initiative, 2019)
- → Land targets and technical guidance (Science Based Targets Network (SBTN), 2024)
- → Freshwater targets and technical guidance (Science Based Targets Network (SBTN), 2024)
- → Sectoral Materiality Tool (SBTN, 2022)
- → Guidance on wastewater and solid waste management for manufacturing of antibiotics (2024) (World Health Organization, 2024)
- → ENCORE (Exploring Natural Capital Opportunities, **<u>Risks and Exposure</u>**) (United Nations Environment Programme)
- → Water Risk Filter Suite V2 (World Wide Fund for Nature, 2025)
- → Antibiotic Manufacturing Standard (AMR Industry Alliance, 2024)

→ Science-Based Predicted No-Effect Concentrations (PNEC) Targets for Risk Assessments (AMR Industry Alliance, 2024)

The following organizations and coalitions also provide useful information for the sector:

- → AMR Industry Alliance (Antimicrobial Resistance Industry Alliance)
- → <u>AWS</u> (Alliance for Water Stewardship)
- → <u>Health Systems Task Force (Sustainable Markets</u> **Initiative**)
- → Pharmaceutical Supply Chain Initiative
- → Pharmaceutical Environment Group
- → PREMIER (Prioritization and Risk Evaluation of **Medicines in the Environment)**
- → Circularity in Primary Pharmaceutical Packaging Accelerator

Additional sector-agnostic resources:

- → Business for Nature's High-level Business Actions on Nature
- → Nature and Biodiversity Peer Group
- → CEO Water Mandate (UN Global Compact)
- → The Natural Climate Solutions Alliance (WBCSD)

#### Glossary

Terminology	Definition
Avoid & reduce (within AR3T)	Prevent impact happening in the first place, eliminate impact entirely.
Bioaccumulation	The accumulation of pollutants in living organisms by direct adsorption or through food chains. United Nations Environment Programme (UNEP), <u>bioaccumulation</u>
Contract development and manufacturing organization	A company that provides drug development and manufacturing services to a pharmaceutical comp
Dependencies (on nature)	Aspects of environmental assets and ecosystem services that a person or an organization relies or of water flow, water quality regulation and the regulation of hazards like fires and floods; provision sequestration. Adapted from Science Based Targets Network (2023), <u>SBTN Glossary of Terms</u>
Feedstock	A raw material going into a chemical process or plant as input for conversion into a product. European Commission, <mark>Feedstock</mark>
Green "hushing"	Understating commitments and progress for fear of greenwashing backlash
Greenwashing	Misleading the public so that they believe that a company or other entity is doing more to protect t United Nations, <u>Greenwashing – the deceptive tactics behind environmental claims</u>
Impacts (on nature)	Changes in the state of nature (quality or quantity), which may result in changes to the capacity or result of an organization or another party's actions and can be direct, indirect or cumulative. A sing Science Based Targets Network (2023), <u>SBTN Glossary of Terms</u> Climate Disclosure Standards Board (2021), <u>Application guidance for Biodiversity- related Disclosur</u>
Just transition	A set of principles, processes and practices that aim to ensure the transition from a high-carbon to Intergovernmental Panel on Climate Change (IPCC) (2022). <u>Annex I: Glossary</u>
Materiality	Report preparers should use the definitional guidance regarding materiality provided by the regulat In the absence of any such guidance, the Taskforce on Nature-related Financial Disclosures (TNFD) to identifying information that is material for users of general financial reports as a baseline. Report materiality approach to identify information in addition to the ISSB's baseline. With respect to impa- language and approach of the Global Reporting Initiative (GRI) Sustainability Reporting Standards. Organizations seeking to align with Target 15 of the Global Diversity Framework (GBF) will want to a global baseline.

npany on a contract basis

on to function. A company's business model, for example, may be dependent on the ecosystem services n of suitable habitat for pollinators, who in turn provide a service directly to economies; and carbon

the environment than it is.

of nature to provide social and economic functions. Impacts can be positive or negative. They can be the gle impact driver may be associated with multiple impacts.

#### <u>ires</u>

to a low-carbon economy leaves no people, workers, places, sectors, countries or regions behind.

atory authorities for their reporting jurisdiction.

) recommends that organizations apply the International Sustainability Standards Board (ISSB) approach ort preparers who want or need to report using a different materiality approach may apply an impact act materiality, the TNFD has aligned its recommendations (and supporting additional guidance) with the s.

consider the application of an impact materiality lens to identify information that is incremental to the

#### Glossary

Terminology	Definition
Natural climate solutions	Actions to protect, better manage and restore nature to reduce greenhouse gas emissions and sto The Nature Conservancy (2024), <b>How nature can fight climate change – and how it can't</b> .
Nature	The natural world, with an emphasis on the diversity of living organisms (including people) and thei Adapted from Díaz, S. et al. (2015), <u>The IPBES Conceptual Framework – Connecting Nature and Peo</u>
Nature positive	A global societal goal defined as "halt and reverse nature loss by 2030 on a 2020 baseline and achieved and entities, geographies and countries can and must demonstrate their sufficient contribution negative and positive impacts is central. Nature Positive Initiative (2023), <u>The definition of nature positive</u>
Nature-based solutions	Solutions that leverage nature and the power of healthy ecosystems to protect people, optimize in International Union for Conservation of Nature, <u>Nature-based Solutions</u>
Nature-related opportunities	<ul> <li>Activities that create positive outcomes for organizations and nature by creating positive impacts Impacts and dependencies on nature generate nature-related opportunities and can occur:</li> <li>When organizations avoid, reduce, mitigate or manage nature-related risks, for example connocures.</li> <li>Through the strategic transformation of business models, products, services, markets and invincementation of nature-based solutions.</li> <li>Adapted from WWF (2022), <u>A Biodiversity Guide for Business</u></li> </ul>
Nature-related risks	In line with the International Organization for Standardization (ISO), the TNFD defines nature-relate society's dependencies and impacts on nature. Risk Management – Guidelines, Taskforce on Nature-related Financial Disclosures (TNFD) (2017), Fin
Precursor (chemistry)	A chemical compound involved in a chemical reaction that produces another compound
Regenerate (within AR3T)	Four actions designed within existing land uses to increase the biophysical function and ecological nature to people (e.g., on carbon sequestration, food production and increased nitrogen and phosp Science Based Targets Network (SBTN) (2023), <u>SBTN Glossary of Terms</u>
Regenerative Agriculture	Agricultural systems that improve the environment, soil, plants, animal welfare, health and commun Regeneration International (2023, <u>The Definition of Regenerative Agriculture</u>

#### ore carbon

eir interactions among themselves and with their environment. <u>ople</u>, Current Opinion in Environmental Sustainability 14: 1–16.

hieve full recovery by 2050."

tion to a global nature-positive outcome. In operationalizing nature positive, tackling drivers and the

nfrastructure and safeguard a stable and biodiverse future.

s on nature or mitigating negative impacts on nature.

nected to the loss of nature and ecosystem services that the organization and society depend on; nvestments that actively work to reverse nature loss, including by restoration, regeneration of nature and

ed risks as potential threats (effects of uncertainty) posed to an organization that arise from its and wider

inal Report: Recommendations on Climate-related Financial Disclosures

al productivity of an ecosystem or its components, often with a focus on the specific contributions of sphorus retention in regenerative agriculture.

inities.

#### Glossary

Terminology	Definition
Restore (within AR3T)	Initiate or accelerate the recovery of an ecosystem with respect to its health, integrity and sustaine Science Based Targets Network (SBTN) (2023), <u>SBTN Glossary of Terms</u>
Science-based targets	Measurable, actionable and time-bound objectives, based on the best available science, that allow
Stakeholders	Persons or groups directly or indirectly affected by a project, as well as those who may have intere Adapted from Shift and Mazars LLP (2015), <u>UN Guiding Principles Reporting Framework</u>
Target	Specific quantitative and time-bound objective, preferably with a defined means of measurement. Science Based Targets Network (2020). <u>Science Based Targets for Nature: Initial Guidance for Busin</u>
Transform (within AR3T)	Actions contributing to system-wide change, notably the drivers of nature loss, e.g., through techno Science Based Targets Network (2023), <u>SBTN Glossary of Terms</u>
Value chain	Production of "economic value" along a series of activities, sites and entities. The value chain has the where economic activities managed or relied upon by the company occur. Most value chain framew management, that (a) supply or add value to raw materials and intermediate products to produce products. Science Based Targets Network (SBTN) (2023), <u>SBTN Glossary of Terms</u>
Watershed	A land area that channels rainfall and snowmelt to creeks, streams and rivers and, eventually, to ou National Oceanic and Atmospheric Administration (NOAA), <u>What is a watershed?</u>
Zoonotic disease or zoonosis	Any disease or infection that is naturally transmissible from vertebrate animals to humans. World Health Organization (WHO), <mark>Zoonoses</mark>

nability, with a focus on permanent changes in state.

w actors to align with the Earth's limits and societal sustainability goals.

rest in a project and the ability to influence its outcome, either positively or negatively.

#### iness

nological, economic, institutional and social factors and changes in underlying values and behaviors.

three segments: upstream, direct operations and downstream. Each of these segments involves places eworks cover a suite of activities starting with the raw materials and extending through end-of-life e final products for the marketplace and (b) are involved in the use and end-of-life management of these

outflow points such as reservoirs, bays and the ocean.

#### Annexes Continued

#### Acronyms

ACT-D	High-level Business Actions on Nature to Assess, Commit, Transform and Disclose	ENCORE
AMR	antimicrobial resistance	ESRS
APIs	active pharmaceutical ingredients	FDA
AR3T	Science Based Targets Network (SBTN) Avoid, Reduce, Restore, Regenerate and Transform Framework	FPIC
BfN	Business for Nature	GBF
BSI	British Standards Institute	GDP
CapEx	capital expenditure	GRI
СДМО	contract development and manufacturing organization	HIC
COP16	The Convention on Biological Diversity's 16th Conference of the Parties	IFRS
COP30	30th United Nations Climate Change Conference	IPBES
CSDDD	European Union Corporate Sustainability Due Diligence Directive	IPCC
CSRD	European Union Corporate Sustainability Reporting Directive	IPLC
DCF	deforestation- and conversion-free	ISIC
DIRO	dependencies, impacts, risks and opportunities	ISSB
DSI	digital sequence information	KBA
EMA	European Medicines Agency	LAL

Exploring Natural Capital Opportunities, Risks and Exposure database

European Sustainability Reporting Standards

United States Government Food and Drug Administration

free, prior and informed consent

Kunming-Montreal Global Biodiversity Framework

gross domestic product

Global Reporting Initiative

Science Based Targets Network (SBTN) High Impact Commodities list

International Financial Reporting Standards

Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services (IPBES)

Intergovernmental Panel on Climate Change

Indigenous Peoples and local communities

International Standard Industrial Classification of All Economic Activities

International Sustainability Standards Board

key biodiversity area

Limulus amoebocyte lysate

#### Annexes Continued

#### Acronyms

LCA	life-cycle assessment	WBA
LEAP	Locate, Evaluate, Assess, Prepare – TNFD's suggested nature-related risk and opportunity management approach	WBCS
MRV	monitoring, reporting and verification	WFI
NbS	nature-based solutions	WHO
NCS	natural climate solutions	
OpEx	operating expense	
PEG	Pharmaceutical Environment Group	
PIE	pharmaceuticals in the environment	
PSCI	Pharmaceutical Supply Chain Initiative	
R&O	risks and opportunities	
SBTN	Science Based Targets Network	
TNFD	Taskforce on Nature-related Financial Disclosures	
UNEP	United Nations Environment Programme	
UNEP-WCMC	United Nations Environment Programme-World Conservation Monitoring Centre	
UWWTD	Urban Wastewater Treatment Directive	
WASH	water, sanitation and hygiene programs	

World Benchmarking Alliance

World Business Council for Sustainable Development

water for injection

World Health Organization

### Endnotes

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## Acknowledgements

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This publication has been developed in the name of WBCSD. Like other WBCSD publications, it is the result of collaborative efforts by representatives from member companies and external experts. A wide range of member companies reviewed drafts, thereby ensuring that the document broadly represents the perspective of WBCSD membership. Input and feedback from stakeholders listed was incorporated in a balanced way. This does not mean, however, that every member company or stakeholder agrees with every word. The Roadmap has been prepared for general informational purposes only and is not intended to be relied upon as accounting, tax, legal or other professional advice.

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