



# DOUBLE MATERIALITY ASSESSMENT REPORT

FY 2025-26

#### **Materiality Assessment**

At Alkem, our sustainability strategy is shaped by a deep understanding of the issues that matter most to our stakeholders and our business. Through a structured materiality assessment, we identify and prioritize ESG topics that have the greatest potential to impact our long-term performance and value creation. In line with evolving global sustainability standards, we have conducted double materiality assessment in the current financial year to deepen our understanding of ESG impacts from both financial and societal perspectives. This approach enables us to evaluate environmental, social, and governance issues affecting our business performance (financial materiality), but also how our operations influence the broader economy, environment, and society (impact materiality). By integrating both dimensions, we aim to build a more resilient and responsible strategy that aligns with stakeholder expectations and regulatory developments. This assessment is being conducted through structured stakeholder engagement, internal analysis, and alignment with global frameworks including EFRAG and GRI guidelines to ensure comprehensive and forward-looking ESG prioritization.

#### **Approach to Materiality Assessment**

The stakeholder engagement forms the cornerstone of our materiality assessment process. We engage a broad spectrum of internal and representatives of external stakeholders-including employees, leadership, shareholders, regulators, suppliers, customers, and community partners-to ensure their perspectives are reflected in our ESG roadmap. By actively involving both internal and external stakeholders, we identify and prioritize ESG issues that are most relevant to our business and the communities we serve. This inclusive approach enables us to uncover ESG-related risks and opportunities, align our strategic planning with long-term objectives, and deliver meaningful value across our stakeholder ecosystem.

We followed the following steps-



To evaluate **impact materiality**, we conducted a thorough analysis of our organizational context, business operations, sector-specific conditions, and stakeholder relationships. This helped us identify both actual and potential impacts across economic, environmental, and social dimensions. Each impact was categorized based on its nature-positive or negative, reversible or irreversible, intended or unintended, and short-term or long-term. We then assessed the significance of the negative impacts by prioritizing

them according to severity (considering scale, scope, and irremediable nature) and likelihood of occurrence.

For **financial materiality**, we systematically identified the risks associated with these impacts and analyzed their potential effects on our financial performance over the short, medium, and long term. This evaluation was led by our senior leadership, who carefully considered both the likelihood and financial significance of each issue.

Based on the analysis, material topics were prioritised and placed in a Materiality Matrix. Our senior leadership reviewed these material topics. We consider the topics identified as significant, and include their mitigation action plans as a part of our enterprise risk management.



Section	No	Topic	Priority
	1	Energy	Medium
	2	GHG Emissions	Medium
Environment	3	Water	High
	4	Waste	High
	5	Biodiversity	Medium
	6	Access to Medicine and Affordability	Medium
	7	Workforce & Human Capital	Medium
	8	Human Rights	Low
Social	9	Occupational Health and Safety	Medium
	10	Patient Safety and Product Quality	High
	11	Counterfeiting of Drugs	High
	12	Labelling & Packaging	Low

	13	Community Impact	Medium
	14	Clinical Trials	Low
	15	Governance	Medium
	16	Ethics	Medium
Covernance	17	Risk Management	Medium
Governance	18	Supply Chain and Responsible Production	Medium
	19	Cybersecurity and Data Privacy	High
	20	Innovation & R&D	Medium

#### Material Issues - Risk and Opportunity

Identified Material Issues	Risk or Opportunity	Rationale for identification	Adaptation/Mitigation Action	Financial implications of the risk or opportunity
Trustworthy Stewardship				
Governance	Risk and Opportunity	Weak governance structures can lead to compliance failures, data inaccuracies, fraud, ethical breaches, and delayed decision making. This can reduce investor trust and expose the company to penalties or reputation loss.  Effective governance helps strengthen market reputation,	We have strengthened board oversight on ESG matters, improved internal controls, set up clear accountability structures, formalise policies for ethics, antibribery, data integrity, and board evaluation systems.  We conduct regular board training on ESG trends, creation of board-level ESG committees, digitising governance systems, and transparent stakeholder reporting.	Better governance reduces the risk of penalties, audit failures, and regulatory actions. It can also improve access to capital, strengthen investor confidence, and reduce the cost of compliance in the long term.  Improved governance can attract

		improve decision making, and enhance long-term value creation.		ESG-focused investors, lower capital costs, and open new partnerships due to improved trust and transparency
Ethics	Risk and Opportunity	Any type of unethical behavior or corporate misconduct in the form of fraud, bribery, corruption, conflicts of interest, or violation of laws and regulations governing the industry may lead to major reputational damages, loss of stakeholder trust, and litigation. Poor corporate governance practices, such as lack of transparency, ineffective oversight, lack of accountability, etc., can impact investor confidence and	We place great emphasis on principles such as empowerment and integrity of our employees, safety of employees, safety of employees and communities surrounding our manufacturing facilities, transparency in decision making process, and fair and ethical dealings with all stakeholders and society in general. Our 9 core values: Quality, Adaptability, Responsibility, Responsibility, Respect, Gratitude, Fairness, Honesty, Safety and Compassion enable the Company to make informed decisions. Moreover, our business relies on various policies and codes such as Code of Business Conduct, Code of Ethics,	Positive implication as good governance improves access to capital.

		shareholder value. On the contrary, a commitment towards ethical conduct and robust corporate governance can increase the Company's market competitiveness and enhance stakeholder relationships.	Whistle-blower Policy, Code of Practices and procedures for fair disclosures, etc., that function as guiding forces, steering the Company's business conduct and shaping behavioral norms	
Risk Management	Risk	Weak risk identification and monitoring can lead to operational disruptions, supply chain failures, safety incidents, or ESG non-compliance. This affects business continuity and increases unexpected costs.	We implement enterprise risk management systems, conduct regular risk assessments, improve supplier risk screening, and integrate ESG risks into business planning.	Avoiding losses from disruptions, reducing insurance premiums, and improving operational stability.
Cybersecurity and Data Privacy	Risk	With increasing instances of data breaches, it is important for a Company to safeguard the sensitive customer data or its proprietary	We have set a goal to obtain ISO 27001 certification by FY 2025-26, demonstrating our commitment to develop robust Information Security Management Systems	Negative implications due to cost incurred in implementing and maintaining cybersecurity technologies

		information and prevent any potential breaches that could harm its reputation and may lead to both financial and non-financial losses.	enforced an Information Security Policy in accordance with Microsoft Active Directory. We are investing adequately in IT tools for data protection. Any data loss or leakage is closely monitored through VAPT and IT audits.	and penalties under applicable data privacy laws.
Innovation & R&D	Opportunity	An evolving healthcare landscape demands innovative solutions and products to address society's unmet medical needs and simultaneously provides opportunity for the Company to expand into newer markets.	into R&D to drive	Positive implications with development of new patents that can generate revenue streams.
Supply Chain and Responsible Production	Risk	Gaps in the pharmaceutical supply chain may likely disrupt the production and distribution of medications, leading to shortages or delays in	We have obtained an Associate Membership with Pharmaceutical Supply Chain Initiative (PSCI) to attain safety, environmental, and social outcomes across its value chain and promote responsible value chain practices.	Negative implications are observed due to potential loss of business in case of supply chain disruption.

		providing essential drugs to patients. The consequences can affect both Company's reputation and public health.	In addition, we have shown our commitment towards sustainability in supply chain by taking targets around screening and evaluating our critical suppliers against ESG practices, while also initiating accounting of our Scope-3 emissions	
Environment Stewardship	<b>.</b>			
Biodiversity	Risk	Biodiversity loss can pose a significant risk to the Company, given the reliance of the pharmaceutical industry on a variety of natural resources and biological compounds. A reduction in biodiversity can lead to a scarcity of medicinal plants and other raw materials critical for drug development (especially in Biosimilars and Nutraceuticals segments), potentially increasing costs and impacting	We are committed to protecting and preserving the natural resources and ecosystem as a part of Environmental Protection in our Sustainability Policy.  Alkem has conducted base level biodiversity risk assessment under Environmental Impact Assessment (EIAs) for all its sites and operates within regulatory measures as specified in its consent to operate by regulatory authorities.  Additionally, as a part of our environment and CSR initiatives, we participate in mass plantation drives to restore green cover.	Negative implications due to cost incurred for the protection of biodiversity.

		Environmental degradation, resulting from operations and new projects undertaken, could also heighten regulatory scrutiny, leading to stricter compliance requirements.		
Climate Change and GHG Emissions	Risk and Opportunity	Risk: The Company's assets are prone to climate-induced physical and transition risks which are anticipated to increase in frequency and/or intensity. Adverse weather events can cause various forms of business disruptions. Additionally, Alkem understands the global urgency of addressing climate change and to reduce increase in average global temperatures. Opportunity: Climate change	Our initiatives and actions are guided by our Sustainability policy that serves as an enabling framework to fulfill our business responsibilities towards addressing climate change and GHG emissions related risks. We have set the targets for reducing Scope 1 and 2 emissions by 42% by FY 2032-33. Additionally, this risk has been included in the Enterprise Risk Management system and appropriate mitigation strategies (at entity level) have been identified to address it. We have also undertaken Scope-3 emissions accounting with an	Negative implications due to adverse impact on Company's assets.

		impacts may lead to various health implications on individuals, thereby necessitating the demand for responsive health care services in the future.	intent to adopt measures to reduce them by engaging with relevant stakeholders.	
Energy	Risk and Opportunity	Risk: The Company's operations are energy-intensive and consume a high amount of fuel and electricity. If not managed well, the Company might have to bear higher operational costs due to energy inefficiencies. Opportunities: Improving the existing processes for increased efficiency, upgrading to new technologies, and switching to greener energy sources will immensely benefit the Company's operations in	We target to achieve Y- o-Y 1% reduction in energy consumption from projected energy requirement for each year till FY 33. Multiple initiatives have been adopted for improved energy management, some of these include:  • Use of PNG Gas in boilers instead of furnace oil at select sites  • Biomass Briquette Boilers installed at sites to minimize the use of traditional fossil fuels  • Installation of Variable Frequency Drive (VFD)  • Replacement of non-efficient Air Handling Unit (AHU) with new efficient AHU  • Additionally, by FY 2025-26, we strive to obtain ISO 50001 for all our operating sites	Negative impact due to cost incurred for the capex of energy efficient equipment; however, positive financial impact projected in long-run due to lower cost of energy.

		terms of improved yield, increased profitability and reduced GHG emissions.		
Waste	Risk	Being in the pharma sector, the Company generates significant quantities of hazardous waste along with other non-hazardous waste, which, if not managed properly, might lead to regulatory noncompliances, fines & penalties, and loss of reputation.	Our emphasis on waste minimization is reflected in its adoption of the 3R principle: Reduce, Reuse, Recycle. We have also tied up with government authorized waste management firms to support the waste management practices in line with the 3R principles. We recycle/reuse 100% of our non-hazardous waste. All hazardous waste generated is disposed as per regulatory mandates, with priority to coprocessing over incineration.	Negative impact due to cost incurred in handling and management of waste.
Water	Risk	Shortage of water resources at the key locations of Company's business operations, including manufacturing and R&D sites,	We have developed a water neutrality strategy as we strive to become water neutral by FY 2029-30. As a part of the strategy, we have identified various demand-side and supply-side water management	Negative impact due to cost incurred in meeting water demand during shortages or availability of poor-quality water.

		can disrupt operations and, hence, business continuity. Availability of poor-quality water is also a concern considering pharma manufacturing demands good quality water to meet product quality standards.	interventions. As a part of some existing initiatives, we focus on reducing freshwater intake by monitoring water consumption, auditing the raw effluent and treated water discharge, and educating the workforce on water saving practices. Rainwater harvesting and effluent treatment plants are set up at all manufacturing sites. Currently, 42% of the manufacturing plants are following Zero Liquid Discharge (ZLD).	
Care for all  Human Rights	Risk	Violation of human rights principles can harm the reputational image of the Company and impair stakeholder trust.	We have a Code of Ethics for all our stakeholders including suppliers, vendors, and contractors, which act as a guiding document to ensure ethical practices in our operations. Human Rights clauses are also covered in our Code of Ethics for suppliers, vendors and other stakeholders ensuring their adherence across our value chain.	Negative implications in the short term due to cost incurred to ensure strict inclusivity of human rights principles within the system and processes through regular audits, training, and compliance measures.

Workforce	&	Human	Opportunity	The industry	We have adopted	Positive
Capital				demands human	appropriate	implications
				capital, which is	enforcement	due to
				knowledgeable,	mechanisms in the	increased
				and skill driven.	form of dynamic	productivity of
				The productivity	Human Resource	workforce.
				and efficiency of	policy framework,	
				employees	Environment Health &	
				associated with	Safety (EHS) Policy,	
				the Company	Sustainability Policy,	
				provides better	and other relevant	
				asset integrity	guidelines. The HR	
				and business	team provides	
				growth alongside	strategic and skill	
				all functions of	development training	
				the business.	to every employee to	
					foster a balance of	
					personal and	
					professional growth.	
					Additionally, we offer	
					our employees an inclusive and	
					supportive	
					environment with	
					suitable employment	
					benefits such as	
					insurance, medical	
					support, maternity	
					leaves, paternity leave,	
					sick leave, support	
					from benevolent funds	
					during emergencies,	
					and access to	
					counseling in case of	
					need. The Company	
					fosters diversity and	
					encourages equal	
					opportunities among	
					its employees, through	
					initiatives such as	
					SHINE program,	

			thereby striving to attract and retain the best talent across all functions and levels.	
Occupational Health & Safety	Risk	Due to the nature of the pharmaceutical industry, the Company's employees and workforce are exposed to hazardous chemicals and substances during the manufacturing and R&D processes, with potential to health hazards.	We are focused on our 'Zero Harm' approach – Zero Harm to People, Assets, and Environment. The Environment, Health & Safety (EHS) policy is applicable across all the sites. All our operational manufacturing sites and R&D facilities are now ISO 45001 certified. We carry out periodic EHS audits on sites to identify the gaps and address them. The culture of health & safety is promoted through extensive health and safety training for both employees and workers. Additionally, multiple initiatives are deployed to ensure process safety and control of chemical exposure.	Positive implications due to increased work productivity and reduced LTIFR.
Community Impact	Opportunity	For a Company to thrive with community entrustment, it is important to consider	We address and support the immediate and long-term needs of the community and focus on creating a positive impact	Positive implication due to goodwill and reputation among the

		community priorities and align business goals with them. Any violating practices can damage Company's reputation and give rise to conflicts. Establishing relationships of trust with communities and ensuring their frequent participation will help the Company contribute to social development and minimize potential objections from the communities	through multiple ways.  Some of these initiatives are focused on improved healthcare, education, rural development, environmental care, and sports culture.	communities, thereby avoiding chances of legal disputes.
Counterfeiting of Drugs	Risk	Presence of counterfeit products in market may seriously harm the Company in multiple ways. The prevalence of spurious products impacts revenue generation as	We are deploying technological interventions with Anti-counterfeiting Security features including QR codes on packaging to ensure traceability of the product.	Negative implications are due to costs incurred in the mitigation plan and potential loss of business.

		well as customer loyalty.		
Patient Safety and Product Quality	Risk	Unintended characteristics of the product may cause health and safety risks for the patients, thereby leading to reputational damage, fines, or penalties, along with loss of customers' trust.	We have a pharmacovigilance system in place to safeguard patient health through efficient and timely identification, collection, assessment, and communication of medicine related adverse events. The Company also strictly adheres to cGMP guidelines which are enforced by regulatory agencies for quality assurance in manufacturing processes. Quality control checks are conducted periodically across facilities for all machinery and equipment to identify and address any noncompliances.	acceptance
Clinical Trials	Risk	The conduct of clinical trials is significant for any pharmaceutical company to ensure safety and efficacy of their products.  Violation of regulatory norms	We ensure adherence to all protocols and regulatory constraints while incorporating ethical conduct in clinical trials. We are dedicated to conducting scientifically robust and ethical clinical	Positive implications due to increased likelihood of regulatory approval of new drugs, potentially speeding up

		and unethical practices in clinical trial may cause delays in drug approvals, inhibit the delivery of commercially viable products, and pose legal consequences	unmet healthcare needs and generate quality data for the development of effective and safe novel molecules. We hold significant experience in conducting clinical trials from phase 1 through phase 4 clinical studies across multiple therapies, in accordance with ICH GCP and several other international guidelines and regulations. Our R&D team has gained extensive experience and expertise in conducting clinical studies on small and large molecules, including monoclonal antibodies and biosimilars, as well as stem cell-based products for domestic and global regulatory submissions like CDSCO, USFDA, and EMEA.	market and increasing revenue streams.
Access to Medicine and Affordability	Risk	As a part of its social and moral responsibilities, it is important for the Company to provide and place	Our R&D facilities work towards innovative solutions to ensure affordability and accessibility of products without	Positive implications in the long run due to increased market share.

		products in the	compromising on	
		markets where	quality.	
		they are	quanty	
		accessible and		
		affordable for the		
		patients. The		
		Company may		
		otherwise lose		
		market share to		
		its competitors,		
		who may offer		
		more accessible		
		and affordable		
		alternatives,		
		resulting in		
		significant		
		decline in		
		Alkem's revenue		
		and profitability.		
		In the long run, it		
		may become difficult to regain		
		customer trust and market		
		position.		
Labelling and Packaging	Risk and	Non-compliance	We have strengthened	Positive
	Opportunity	with labelling	labelling review	implication
	opportunity	requirements or	<u>-</u>	due to
		inaccurate	digital systems for	avoiding of
		product	traceability, and	compliance
		information can	ensure compliance	penalties,
		lead to regulatory	with FSSAI and sector-	reducing
		penalties,	specific standards.	recall-related
		product recalls,	specific stantuarus.	losses, and
		and loss of		lowering long-
		consumer trust.		term
		Excessive		packaging
		packaging also		costs through
		exposes the		material
		company to rising		optimization.
		company to rising		optimization.

EPR-related costs. Sustainable		Premium pricing opportunities
packaging	and	for sustainable
accurate labe	lling	products,
can enha	ance	reduced
brand credib	ility,	packaging
improve		material cost
consumer		in the long run,
preference,	and	and stronger
differentiate	the	brand loyalty
product	in	leading to
competitive		higher sales.
markets		
		1

#### **Material Issues for External Stakeholders**

Material Issue	Impact	Impact
Material Issue for External	Water Management	Waste Management
Stakeholders		
Cause of the Impact	Business value chain -Operations	Business value chain:
	Business activity coverage: >50%	Operations
	of business activity	Business activity coverage:
		>50% of business activity
External	Environment, Society, Consumers	Environment, Society,
stakeholder(s)/impact area(s)		Consumers, and External
evaluated		employees (Contractors,
		Logistic partners etc.)
Topic relevance to external	Water-related risks translate into	Alkem generates diverse waste
stakeholders	significant external impacts across	streams—including hazardous
	environmental, social, and	chemical waste, packaging
	consumer dimensions.	waste, biological waste,
	a. Environmental Impact	solvent residues, and
	a. Environmental impact	contaminated materials—each
	Pharmaceutical operations often	of which carries potential
	rely on high volumes of	impacts on environmental and
	freshwater and generate complex	
	effluents that require stringent	

treatment. If not managed responsibly, water extraction can contribute to local groundwater stress, especially in water-scarce regions. Untreated or poorly treated effluents containing chemical residues, solvents, intermediates, and high total dissolved solids can adversely affect aquatic ecosystems, reduce biodiversity, and alter downstream water quality. The presence of active pharmaceutical ingredients (APIs) in discharged water also poses ecological risks such as endocrine disruption and antimicrobial resistance development.

### b. Societal Impact (Communities and Public Health)

Communities surrounding pharma facilities depend on the same water sources the industry draws from. Excessive withdrawal can affect community access to drinking water, agriculture, and livelihoods. Effluent mismanagement can lead to odour, contamination, or visible degradation of local water bodies, affecting community health and trust.

#### c. Consumer / End-user Impact

Alkem being an API manufacturer, untreated water discharge may contribute to environmental antimicrobial resistance, which social systems, end-users, and supply chain workers.

#### a. Environmental Impact

Improper management of hazardous waste can lead to soil contamination, groundwater pollution, and ecological degradation. Chemical residues, solvents, expired intermediates, and API-laden waste can persist in the environment and disrupt ecosystems. Incineration of waste without proper emissions control may contribute to air pollution and GHG emissions. In addition, plastic and multilayered packaging waste from pharma production and distribution can accumulate in landfills or natural environments.

## b. Societal Impact(Communities and Public Health)

Communities near manufacturing or disposal sites may face health risks if pharmaceutical or chemical waste is not handled properly. Odour, leakages, open burning, or spills can contribute to respiratory issues, waterborne diseases, and long-term health impacts. Large volumes of packaging waste entering municipal waste streams create additional burdens for

	ultimately threatens global health	local waste workers and civic
	outcomes and consumer safety.	infrastructure.
	,	
	Type of Impact:	c. Consumer / End-user
	Negative	Impact
		enters informal markets such as expired drugs or disposed packaging may contribute to counterfeiting or misuse, affecting consumer safety. Improper disposal of returned or rejected batches also risks
		contamination of supply chains or accidental exposure. There is a potential of antimicrobial resistance in absence of proper hazardous waste management impacting public health globally.
		d. External Employees (Supply Chain, Contractors, Logistics partners)
		Chain, Contractors, Logistics partners)  Supply chain partners and contractors often manage transport, handling, segregation, and disposal of hazardous waste, placing them at higher exposure risk.  Inadequate training, poor labeling, or non-compliant storage can result in accidents, chemical burns, or long-term occupational health issues.
		Chain, Contractors, Logistics partners)  Supply chain partners and contractors often manage transport, handling, segregation, and disposal of hazardous waste, placing them at higher exposure risk.  Inadequate training, poor labeling, or non-compliant storage can result in accidents, chemical burns, or long-term occupational health issues.  Type of impact: Negative
Output Metric	Percentage of sites with no effluent discharge: In FY 2024-25, 92% of our manufacturing sites	Chain, Contractors, Logistics partners)  Supply chain partners and contractors often manage transport, handling, segregation, and disposal of hazardous waste, placing them at higher exposure risk.  Inadequate training, poor labeling, or non-compliant storage can result in accidents, chemical burns, or long-term occupational health issues.

	and R&D facilities did not discharge any effluent.  Percentage of water neutral sites:  We have a target to achieve water neutrality at 100% of our sites by	hazardous waste was recycled/reused.  Percentage of waste diverted from landfill: In FY 2024-25, we diverted 97.65% waste
	FY 30. To achieve the same, we have initiated integrated community watershed management projects at two of our manufacturing units.	from landfill.
Impact Valuation	Impact valuation conducted for environmental value gained.	Impact valuation conducted for environmental value gained.
Impact Metric	% reduction in water withdrawal intensity per tonne of product generated – 7.45%	Environmental value gained through avoided cost of landfilling – INR 10 million