# 1. Applicability

This Sector Profile is designed to help financial institutions (FIs) quickly familiarise themselves with the most frequent and important environmental and social (E&S) aspects of credit facilities in the pharmaceuticals sector. It aims to be a starting point for thinking about E&S risks and opportunities, and not a detailed technical guidance document.

- Using this Sector Profile
  Any company can be affected by non-sector specific issues such as impacts on Indigenous Peoples and cultural heritage. Therefore, each company must be carefully considered based on its specific characteristics and circumstances including scale of operation, location, technology utilised, management capacity, supply chains, commitment and track record. Additionally, the environmental and social (E&S) impacts, risks and opportunities in a particular company or sector can change over time (e.g. changes in the applicable laws, or expansion of a company's activities or assets). FIs should have systems in place to identify such changes and manage any associated risks and impacts and, where possible, capitalise on new opportunities.

  This Sector Profile draws on internationally recognised good practice standards and guidance, particularly the International Finance Corporation (IFC) Performance Standards and the World Bank Group Environmental, Health and Safety (EHS) Guidelines. The Sector Profile identifies key criteria that are generally applicable to each sector (See: 'Standards, guidelines and other resources' section below). It is not a substitute for such standards, which should take precedence as authoritative sources and basic technical references. Applicable laws and regulations must be considered and compliance with them should be regarded as the minimum acceptable performance standard. Situations/transactions in which the FI (i) would conduct E&S due diligence against international standards and/or (ii) require its clients to comply with such standards shall be determined by the FI's E&S management system(s) (ESMS).

  See Resources for indicative questions/checklists that a FI should ask/use when assessing a transaction in the sector.

- Scope of this Sector Profile

  This pharmaceuticals Sector profile covers business activities commonly undertaken in

the manufacture and supply of pharmaceutical products, including:

- Research and development.
- Manufacture of active pharmaceuticals and biotechnology products.
- Formulation, packaging and distribution.

Unless otherwise stated, the risks, impacts and opportunities outlined below relate to the operational phase of business activities. Generic guidance on E&S risks, impacts and opportunities associated with project design and construction of pharmaceutical facilities is provided in the CDC Project Design and Construction Guide.

## 2. Key environmental and social aspects

This section outlines some of the specific risks and impacts that emerge from poor E&S practices. Weak management of these issues can lead to reputational damage, reduce a company's capacity to raise funding (debt and equity) and, more broadly, damage a company's financial performance. Conversely, sound E&S practices are likely to improve a company's reputation, access to credit and overall performance.

- Management commitment, capacity and track record (CCTR)

  Companies need management's commitment and sufficient capacity to ensure that the necessary resources are available for sound E&S management. Refer to CDC Guidance: Assessing Companies' Commitment, Capacity and Track Record.

- Environmental and social management system (ESMS)
  Companies should develop and implement an ESMS commensurate with the level of risks and impacts associated with its activities. For further advice refer to CDC E&S Briefing Note: Company level E&S management system.

- Product quality control and quality assurance

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| **Risks for the business** | - Permanent or temporary loss of licence to operate due to breaches of the applicable quality control regulations.<br>- Direct and indirect costs of quality failures (e.g. lost production, fines and reputational impacts).<br>- Lack of access to markets where entry requires certification/ meeting certain quality requirements. |
| **Opportunities for the business** | - Operational benefits and sales/margin growth resulting from the implementation of an internationally recognised quality system (e.g. Q10 Pharmacutical Quality System) and demonstrable adherence to regulation (e.g. Quality Systems Approach to Pharmaceutical CGMP Regulations).<br>- Access to markets can be enhanced where approved supplier or certification programmes include E&S requirements related to product quality.<br>- Sales/margin growth through ability to meet the requirements of trade buyers whose approved supplier programmes include E&S requirements. |

Pharmaceutical product quality is of critical importance, as it is paramount to ensure that products are in appropriate condition for human consumption. This requires assessing not only at the manufacturing plant but also within all the various stages of the supply chain from production to final consumption, including transportation and storage.

It is also important that any risks associated with counterfeit production are mitigated. If significant product quality issues are identified or recognised as being likely to arise in a company, they should be addressed as a matter of priority.

Therefore, a company must implement and maintain a system to ensure appropriate quality standards. This system should cover suppliers, contractors and distributors, as well as the production facilities themselves, and include:

- Adherence to international Good Manufacturing Practice (GMP).
- Effective implementation of an effective quality system such as Q10 Pharmaceutical Quality System.
- Product recall and counterfeit pharmaceuticals control procedures.
- Certification to international quality management system standards, if

appropriate.

For further guidance refer to the Q10 Pharmaceutical Quality System and the Good Manufacturing Practice.

- Labour and working conditions
  *Note – Occupational health and safety is covered separately below.*

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| **Risks for the business** | - Financial, reputational and legal risks and lower production efficiency can result from poor morale, industrial action, high staff turnover and deterioration of employees' health (e.g. excessive working hours).<br>- Companies may face prosecution or fines (or having their licences removed) if they fail to comply with labour laws and regulation<br>- Poor working conditions can lead to high staff turnover, resulting in increased recruitment and training costs. |
| **Opportunities for the business** | - Good working conditions can reduce costs and enhance productivity, making it easier for the company to attract and retain motivated and competent workers.<br>- Access to markets and finance can be enhanced, if the business achieves certain standards and/or related certifications covering labour and working conditions (e.g. SA 8000). |

**Wages and working hours:** Workers in the sector may be relatively well paid compared to other industries, however there may be significant wage discrepancies depending on the nature of work and skill levels, especially in emerging markets. Workers should be paid at least the minimum statutory wage and overtime should be compensated at an appropriate level. Working hours should not exceed applicable laws or sector agreements. Companies should not use third party contractors as a means of exceeding working hour regulations or avoiding minimum wage payments.

**Equal opportunities and non-discrimination:** The rights of workers to enter free and voluntary collective bargaining arrangements with management should always be respected. Failure to respect these rights and to establish a good relationship with unions could have negative impacts on a company (e.g. strikes). Collective bargaining can be a constructive forum for addressing working terms and conditions and to improve worker/employer relations. It is often more effective and more flexible than

state regulation. It can help to anticipate potential problems and can advance peaceful mechanisms for dealing with such problems in a way that takes into account the priorities and needs of both employers and workers

**Child labour, bonded and forced labour:** Non-compliance with ILO Core Labour Conventions on Child Labour / Minimum Age and Forced Labour is not acceptable under international standards. Where not already in place, measures to eradicate these forms of labour should be implemented as a matter of priority.

**Freedom of association and collective bargaining:** Relations with unions and the rights of workers to enter free and voluntary collective bargaining arrangements with management (as well as the rights to form unions and to participate in industrial action) may be sensitive subjects and require careful exploration and resolution. Where pharmaceutical companies form part of regional or national supply chains and markets, any strikes or wage bargaining challenges can have widespread repercussions on market supply, product pricing or even national competitiveness. Adequate access to grievance mechanisms and attention to business integrity and governance principles are also important. Adopting international good practice in this area can help to manage costs relating to recruitment, training and talent retention and enhance productivity. Co-operation with government and national manufacturing associations can improve conditions for the industry as a whole, including migrant workers.

**Supply chains:** Pharmaceutical companies are often part of complex supply chains and it is important to assess labour and working conditions risks throughout this chain to protect a company's brand and market. Companies should strive to reduce risks of poor labour and employment practices, even where there is no leverage to effect change. This can be accomplished by shifting to those suppliers with better practices or by engaging with poorer quality suppliers to enhance employment and labour practices. This may require collaboration with other manufacturers, regulators and NGOs. Supply chain risks feature in all aspects of the sector including supply of raw materials (risk of poor E&S practices in primary processing), transportation of raw materials or finished products etc. Companies should work towards applying sustainable sourcing principles. For further guidance on supply chains, refer to the E&S topic: Supply chains.

For further general guidance on Good International Industry Practice (GIIP) relating to labour standards and working conditions (in line with ILO Core Conventions), refer to

CDC E&S Briefing Note: Labour Standards and IFC Performance Standard 2: Labor and Working Conditions, and IFC Good Practice Note: Non-Discrimination and Equal Opportunity.

- Occupational health and safety (OHS)

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| **Risks for the business** | - Companies may face prosecution or fines (or have their licence revoked) if workers or contractors are injured or killed.<br>- Damage to, or loss of the company's assets, production, clients or market share.<br>- Increased insurance premiums and legal claims (both in the short- and long-term) can result from poor OHS practices.<br>- In this sector, effective OHS and Process Safety management systems and procedures (e.g. carcinogen control, pathogen / biological / radiological hazard control and major accident hazard control) are critical from both an environmental and social perspective to avoid health impact, liability and reputational risks.<br>- Low workforce morale and erosion of trust can lead to higher staff turnover, lower productivity, additional training and recruiting costs, reduced product quality and reputational damage. |
| **Opportunities for the business** | - Proactively involving workers and contractors in key decisions can help to identify and maintain good OHS practices and improve their acceptance if new or significantly different to previous practices.<br>- Productivity can be improved and insurance premiums for workers' and compensation payments can be reduced.<br>- Market access can be enhanced if a company achieves certain standards and/or certifications that cover OHS matters (e.g. Responsible Care). |

OHS is an important consideration for any business, regardless of sector. All companies must have in place appropriate OHS and emergency preparedness and response management systems, commensurate with the level of risks.

For operational and maintenance activities, companies should implement measures to ensure employees and contractors work in accordance with applicable regulations and Good International Industry Practice (GIIP). Such measures should be covered in companies' OHS, Process Safety and Emergency Preparedness and Response

management systems.

Specific OHS risks in the fishing industry include those in connection with:

- Physical hazards (e.g. use of heavy machinery and vehicles, manual handling, repetitive work, injury or death due to falls from height, strain injuries from heavy lifting, ergonomic stress, work in confined spaces and risk of confinement, use of high pressure equipment including water jets).
- Chemical hazards (e.g. handling of hazardous toxic, noxious chemical reagents or allergenic elements such as lead, nickel or chromium or exposure to synthetic hormones and other endocrine disruptors).
- Exposure to heat (e.g. high-pressure steam and hot liquids) and cold (e.g. working in refrigerated areas).
- Exposure to and potential inhalation of toxic fumes such as Volatile Organic Compounds (VOCs) from recovery, isolation and extraction activities and airborne dusts in tablet processes.
- Biological hazards (e.g. pathogens in laboratory and fermentation processes).
- Exposure to noise from fixed equipment and utilities such as compressed air, vacuum sources and ventilation systems in use in manufacturing areas.
- Exposure to ionising radiation (e.g. use of radiological materials within research and development operations).
- Electrical hazards (e.g. from overhead wires or power to plant and equipment).
- Security (e.g. production of high-value products). Measures should be implemented to ensure that security forces are appropriately trained in the use of force and respect workers' rights.
- Fire, explosion and process safety risks (e.g. use of hazardous materials (toxic, reactive, flammable or explosive compounds) and complex chemical reactions).

For sector specific guidance refer to the World Bank Group EHS Guidelines for

Pharmaceuticals and Biotechnology Manufacturing. Manufacturing industry specific OHS risk management is addressed in more detail in the ILO's online Encyclopedia of Occupational Health and Safety.

For further general guidance on GIIP relating to OHS, refer to CDC Briefing Note: Occupational Health and Safety, IFC Performance Standard 2: Labor and Working Conditions, World Bank Group General EHS Guidelines, World Bank Group EHS Guideline for Pharmaceuticals and Biotechnology Manufacturing and the CDC Good Practice: Preventing Fatalities and Serious Accidents.

- Pollution prevention and resource efficiency

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| **Risks for the business** | - Fines and penalties can be imposed for non-compliance with national pollution prevention standards, especially with respect to air emissions (process emissions may be high in NOx, SOx, particulate matter and greenhouse gases) and effluent quality. In extreme cases, companies can have their license to operate revoked.<br>- Major fines, penalties and reputational risks due to the occurrence of accidents (e.g. major chemical spills or accidents involving the release of hazardous materials to the environment or the endangerment of communities). In extreme cases, companies can have their license to operate revoked.<br>- Excessive expenditure on energy, water and/or other production inputs.<br>- Excessive expenditure on management of emissions, solid waste and wastewater quality. |
| **Opportunities for the business** | - Lower operating costs, reduced environmental footprint and better preparedness for resource shortages.<br>- Preparedness for regulatory changes such as implementation of a carbon tax, more stringent emissions standards.<br>- Cost savings or new revenue can be generated by careful handling, storage and disposal of waste, including investigating additional processing or reuse of waste for use as raw material in other industries.<br>- Market access can be enhanced if a company achieves certain standards and/or certifications that cover resource efficiency matters (e.g. Responsible Care). |

**Air emissions:** Volatile organic compounds (from chemical synthesis and extraction), acid gases (from thermal oxidation) and particulates (from milling, formulation and tableting) are often emitted during pharmaceutical manufacturing activities from both point sources and as fugitive emissions. Greenhouse gas emissions are also of significance. These are all of particular concern in older equipment. Moreover, air emissions regulations are generally becoming more stringent globally and companies should be mindful of this trend.

In the case of existing plants or expansions or when sourcing pre-owned machinery, retrofitting equipment in order to achieve alignment with GIIP may require additional time and resources. Companies and FIs should set realistic timelines and give due consideration to how Best Available Techniques (BAT) for management of emissions may be applied. The European Integrated Pollution Prevention and Control Bureau (IPPC) offers guidance on BAT for emissions control through its Directive and the associated industry specific BAT reference documents (BREFs) and specifically for Manufacture of organic fine chemicals.

**Water management:** Wastewater streams from pharmaceutical sector activities depend on the specific process and may include chemical reactions streams, product wash water, spent acid and caustic streams, condensed steam from sterilisation and strippers, scrubber blowdowns and facility wash water. These streams may incorporate high biological or chemical oxygen demand, total suspended solids, ammonia, toxicity and pH. Other chemical compounds may also be present including solvents, organic & inorganic acids, cyanide and active pharmaceutical ingredients. Effluent should be carefully disposed of to prevent pollution to underground or surface water sources, or endangering surrounding communities. Pre-treatment may be required. Depending on the nature of the process, techniques for treating process wastewater in this sector include segregation and pretreatment of concentrated wastewater streams, especially where active ingredients are present. Typical wastewater treatment steps may include grease traps, skimmers, dissolved air flocculation, oil water separators, filtration, sedimentation, biological treatment (e.g. aerobic treatment to reduce BOD), chemical neutralisation, disinfection (e.g. chlorination) and dewatering to remove solid residues for separate disposal. Additional treatment may be required where effluent contains metals, VOCs, recalcitrant organics and active ingredients, residual colour or nuisance odour.

Companies should explore opportunities to reduce water consumption (e.g. through use of closed-loop water systems). This is particularly relevant when water

consumption is significant and/or water availability may be or may become restricted. Water use efficiency measures can reduce the amount of wastewater generated and reduce wastewater treatment costs and/or discharge fees.

**Waste management:** Bulk manufacturing processes in the pharmaceutical industry are typically characterised by a low ratio of finished product to raw material resulting in significant quantities of residual waste, especially during fermentation and natural product extraction. Process wastes might include spent solvents, reactants, spent acids and bases, aqueous or solvent liquors, cyanides and metal waste in liquid or slurry form as well as filter cakes. Other sources of hazardous or potentially hazardous wastes may include raw materials packaging waste, off-spec and expired products, laboratory wastes, sludge from wastewater treatment and collected particulate from air emission abatement systems.

Companies must ensure that even small volumes of potentially hazardous waste (e.g. machinery oils, lubricants, solvents, containers that housed these substances etc.) are documented, stored, handled, transported and disposed of in accordance with GIIP and in a manner that prevents environmental contamination or danger to workers or nearby communities. Potentially pathogenic waste from biotechnology manufacture should be inactivated through sterilisation or chemical treatment prior to disposal. Companies should seek to adopt waste reduction strategies consistent with the waste hierarchy to minimise the requirement for waste disposal. Pharmaceutical companies should take particular care in appropriately disposing of waste product packaging materials to mitigate risk of its use in counterfeit products or on the black market.

**Hazardous material management:** In common with other areas of manufacturing, pharmaceutical and biotechnology operations should assess the risks associated with the use and handing of hazardous materials and implement practices to prevent and minimise such risks. A hazardous materials management plan should be developed and implemented in order to establish preventive actions against accidental release of substances that could cause hard to the environment, and the health and safety of workers and surrounding communities. Such a plan should include in implementation of an Emergency Preparedness and Response Plan. Given industry-specific activities including complex chemical reactions, use of toxic, reactive, flammable and explosive materials and use of pressure vessels, process safety programs should also be implemented. These programs should include hazard analysis studies, physical testing of materials and reactions, preventive maintenance and mechanical integrity programs, development and use of operating instructions, procedures for management

of change and work control and ongoing worker training.

For sector specific guidance refer to the World Bank Group EHS Guidelines for Pharmaceuticals and Biotechnology Manufacturing.

For further general guidance on GIIP relating to resource efficiency and pollution prevention, refer to CDC E&S Briefing Note: Resource Efficiency, CDC E&S Briefing Note: Pollution Prevention, IFC Performance Standard 3: Resource Efficiency and Pollution Prevention, and World Bank Group General EHS Guidelines. If Indigenous Peoples may be affected, refer to IFC Performance Standard 7: Indigenous Peoples.

- Community health, safety and security

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| **Risks for the business** | Social licence to operate can be put at risk if social impacts and/or community relations are not well managed. Financial risks if surrounding communities are exposed to acute or long-term health and safety risks from air emissions, waste generation, and/or pollution caused by either manufacturing or research and development activities. Financial risks due to competition for resources such as water and energy with surrounding communities. The company's license to operate can be put at risk if communities feel threatened by, for example pollution or health impacts or by company employed security forces. Reputational damage and significant management costs can be incurred by non-transparent hiring practices, or the exclusion of locally sourced labour or operating hours that result in high levels of noise, traffic or dust for the local community. |
| **Opportunities for the business** | Good community relations help to manage expectations and identify any concerns (e.g. health or safety risks) prior to these becoming risks for company. Reduced security risks, which may indirectly yield other benefits such as improved health and safety of the workforce (if it is at least in-part drawn from the local community). Proactive and positive engagement or employment of local community members can also reduce risk in the company's operations through, for example, increased uptake of safe manufacturing procedures or road safety. |

The most significant community health and safety hazards associated with the pharmaceutical and biotechnology sector occur associated with operational manufacturing, except for those aspects related to quality assurance and ensuring that

products are suitable for human consumption (covered earlier in this Briefing Note). These include the threat of major accidents related to fire and explosion and the potential for accidental releases of finished products or intermediaries from the process or during their transport outside of the manufacturing facility.

**Quality assurance and product safety:** In this sector, it is paramount to ensure that all products are suitable for human consumption. This requires significant control throughout the supply chain and is one of the reasons that this is generally a very heavily regulated sector. Refer to section on Product quality control and quality assurance above.

**Emergency preparedness and response:** Companies must develop and implement emergency preparedness and response plans to respond to emergencies associated with the company's activities in a manner appropriate to prevent and mitigate any harm to people and/or the environment. Companies should develop these systems in collaboration with appropriate and relevant third parties (e.g. local authorities, emergency responders and communities).

**Safety:** Pharmaceutical manufacturing may pose chemical exposure or physical safety risks to local communities through potential fires and explosions on site (e.g. from the management, storage and transport of hazardous solid, liquid and gaseous materials). Such hazards should be prevented through the implementation of a Process Safety Management Program. These programs should include hazard analysis studies, physical testing of materials and reactions, preventive maintenance and mechanical integrity programs, development and use of operating instructions, procedures for management of change and work control and ongoing worker training. The use of large trucks on local roads (for raw material delivery and distribution of finished product) also poses traffic threats. Emergency preparedness focused on protecting local communities should be a priority.

**Security:** Some pharmaceutical manufacturing plants employ or contract specialist security personnel in order to prevent theft or access by external parties for potential safety, theft, sabotage and terrorism reasons. Companies should be guided by the principles of proportionality, GIIP and applicable law in relation to hiring, rules of conduct, training, equipping and monitoring of security personnel. Such principles include practices consistent with the United Nation's (UN) Code of Conduct for Law Enforcement Officials and UN Basic Principles on the Use of Force and Firearms by Law Enforcement Officials.

- Bioethics
  The ethical issues faced by the pharmaceutical industry are potentially complex and depend on the activity of the company. These issues may include the development of genetically modified organisms, gene therapy experiments and stem cell research, human participant trials, animal testing, handling of genetic information and the creation of transgenic organisms. Bioethics management approaches include the establishment of ethics mechanisms including management commitment, access to and use of external expertise, internal training and accountability, communication programs with suppliers and external stakeholders and assurance mechanisms. Companies should adhere to local and internationally accepted ethical principles and standards.

- Antimicrobial Resistance
  The biopharmaceutical sector has a vital role to play in reducing antimicrobial resistance (AMR). This role is particularly important for manufacturers that produce antibiotic active pharmaceutical ingredients (APIs), companies that conduct pharmaceutical and vaccine research and development (R&D), and companies that distribute or sell antimicrobials.

  Proactively identifying and managing AMR risks and impacts can put companies ahead of the curve, helping them to reduce operating risks, and avoid regulatory penalties or public censure. Investors are in a unique position to set market-leading requirements linked to AMR, and support companies through the implementation and monitoring of those requirements.

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| **Risks for the business** | Reputational damage, fines and penalties due to environmental pollution from the production of antimicrobials. Negative media coverage and civil society campaigning if companies do not take actions to reduce AMR. Negative implications on business due to the changing legislative landscape regarding antimicrobials production and distribution, potentially causing significant operational disruptions. Lack of access to markets where entry requires certification or meeting certain quality requirements for antimicrobials. Stranded assets in more profitable business lines (e.g., oncology) as AMR renders treatments and common procedures unsuccessful. |

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| **Opportunities for the business** | Development of new antibiotics and vaccines could receive big financial rewards as governments (e.g. G7 and G20) explore the implementation of pull incentives such as market entry rewards. Improved brand value and reputation if reducing AMR becomes part of company strategy. Preparedness for regulatory changes regarding the production and distribution of antibiotics. Access to markets can be enhanced where AMR is part of environmental and social management systems (ESMS). Upward trends in sustainable procurement make it likely that responsible manufacturers will have more opportunities to win contracts and tenders. |

**Measures to reduce AMR**

- **R&D:** Dedicate efforts to the development of antibacterial and antifungal medicines and vaccines, as well as producing innovative medicines that target priority pathogens.

- **Enhance access in low and middle income countries:** Provide access to antibacterial and antifungal medicines in ‘access countries’. Pharmaceutical companies can also partner with various organisations to register new and essential antimicrobials in those countries, ensuring products are affordable and available in adequate supplies, and that falsified medicines do not enter the supply chain.

- **Ensure effective environmental risk-management strategies:** Implement measures to reduce the environmental impact of antimicrobials by setting science-based discharge limits. Pharmaceutical companies should also require suppliers and private waste treatment plants meet the same environmental standards.

- **Implement responsible promotional practices:** Reduce negative incentives to prevent and control AMR by decoupling bonuses from sales volumes, or not using any sales staff at all, removing the incentive to oversell antibiotics.

- **Contribute to national, regional and global surveillance systems:** Help track antimicrobial resistance trends and antimicrobial consumption patterns by collecting and sharing raw data through the development of surveillance systems.

- **Mitigate conflicts of interest when engaged in educational activities:** This could include accreditation from an independent body that evaluates potential conflicts or provide unrestricted grants to independent third parties to develop educational programmes.

- Include AMR as a core component of communication and educational programmes: Train employees about effective stewardship of the products.

Several multilaterals, development banks and major drug manufacturers now recognise AMR as one of the pre-eminent threats to human health globally. They have been putting together resources and capabilities to strengthen and accelerate the R&D of antibiotics and to encourage best practice among stakeholders. For example:

- The AMR Action Fund aims to bring two to four new antibiotics to patients by 2030. It was launched by 20 biopharmaceutical companies in collaboration with EIB, Wellcome Trust and the World Health Organisation. Together they will invest $1 billion through equity or debt in smaller biotech companies, and will provide industry expertise to support the clinical development of novel antibiotics.

- Wellcome Trust, Pfizer and the governments of Ghana, Kenya, Malawi and Uganda created the Surveillance Partnership to Improve Data for Action on Antimicrobial Resistance (SPIDAAR) to provide valuable data on the impact of drug-resistant infections on patients.

- Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator (CARB-X) is a global non-profit partnership dedicated to accelerating antibacterial research to tackle the global rising threat of drug-resistant bacteria. It is funded by the US Department of Health and Human Services Biomedical Advanced Research and Development Authority (BARDA), the Wellcome Trust, Germany's Federal Ministry of Education and Research (BMBF), the UK Government's Global Antimicrobial Resistance Innovation Fund (UK GAMRIF), the Bill & Melinda Gates Foundation, and receives in-kind support from National Institute of Allergy and Infectious Diseases (NIAID), part of the US National Institutes of Health (NIH).

Further resources: The AMR Benchmark: independent report on pharma's response to

AMR (2020)

## 3. Business integrity considerations

FIs should ascertain and continue to ensure that every company (regardless of sector) complies with the FI's business integrity requirements. For further information, see Business integrity.

- Business integrity issues specific to the pharmaceutical sector.

  The Pharmaceutical sector and associated manufacturing operations is particularly high risk, although the level of risk varies across different pharmaceutical product lines and geographies. In addition to standard business integrity concerns, risks that are particularly relevant for the pharmaceutical sector include:

  - Joint ventures with partners not following good international business integrity practice.
  - Awarding of licenses or payments related to sales contracts.
  - Export and import of goods.

  In order to mitigate corruption risks in the sector, FIs should pay particular attention to the way companies negotiate government sales contracts and the import and export of goods. It is also important that manufacturing companies conduct thorough due diligence on any joint venture partners to prevent corrupt payments being made on their behalf.

## 4. Advice for financial institutions

See also Resources and Transaction Cycle.

- Sector risk overview
  Several E&S issues may be material to the long-term value of education companies, depending on the specific circumstances and geographies of each company. FIs should expect to find that while the E&S risks and impacts can be complex, they can usually be addressed through the application of widely-used, proven techniques and management practices (although this will need to be assessed on a case-by-case basis). External consultants can be engaged to advise on E&S matters, depending inter alia on the nature, scale and location of a company's operations, its track record and the FI's expertise and capacity to conduct appropriate E&S due diligence (DD).

  It should also be noted that corruption risks can be high. Therefore, it is critical that FIs assess all business integrity issues during DD and insist that companies having strong systems in place to mitigate any operational risks.

  Additionally, FIs should bear in mind that the sector is under increasing scrutiny from regulators, stakeholders in the supply chain, consumers and NGOs in relation to product quality, OHS and broader E&S issues.

  FIs should take note of any applicable Exclusion Lists (e.g. CDC's Exclusion List – See CDC Code of Responsible Investing – Schedule 6), which highlight sectors and activities not financed by these institutions. Development Finance Institutions' (DFIs) Exclusion Lists typically include the production of, or trade in, any pharmaceutical products deemed illegal under applicable national regulations or subject to internationally agreed phase-outs or bans as defined in global conventions and agreements.

- Scoping considerations
  In addition to the aspects highlighted above linked to the company's assets, activities and workers, FIs should take into account the following during the life of the credit line, from screening to paydown:
    - **Associated facilities:** Such as access roads, transmission lines or additional downstream processing or distribution activities not operated by the company but on which the company is dependent.

    - **Contractors:** Whose operations present significant E&S risks and impacts, which could have an impact on the business (e.g. construction or maintenance contractors, security services or road transport contractors).

- **Supply chains:** Where these could present significant E&S risks and impacts (e.g. labour or OHS risks). Even where a company cannot directly address risks because it lacks leverage or commercial influence, it is important that FIs are aware of the risks.. Refer to CDC E&S Briefing Note: Supply Chains.

- Situations requiring extra attention

  Extra attention, longer timescales and enhanced E&S DD may be required in more complex situations. This may require engaging external consultants to conduct a gap analysis against the applicable local and international E&S standards (usually IFC Performance Standards and World Bank Group EHS Guidelines). Refer to CDC Guidance: Working with Consultants. See CDC Project Design and Construction Guide.

  Examples of activities or Projects in this sector include:

  - New Projects/expansions: Greenfield construction, major expansion Projects where the scale of operations carries a high risk of major social or environmental impacts, Projects involving land acquisition or where the site is in a sensitive location (e.g. close to protected natural habitats). See CDC Project Design and Construction Guide.

  - Water use: Water-intensive businesses in locations that are subject to significant water scarcity, especially where there is the potential for competition or conflict with other water users such as local communities.

  - Community health, safety and security: Situations/ Projects involving significant risks to, or adverse impacts on, local communities.

  - Protected/Critical Habitats: Situations where conversion of natural habitats or proximity to protected areas or Critical Habitats is evident or likely. Additionally, where development may impact the area's ability to continue to provide ecosystem services (e.g. water and energy to local communities).

  - Economic and physical displacement: Situations/ Projects involving physical and/or economic displacement (e.g. resettlement).

- Cultural heritage: Situations/ Projects involving impacts on cultural heritage (e.g. sacred sites).
- Indigenous Peoples: Companies/activities involving potential adverse impacts on Indigenous Peoples or other vulnerable groups, including restricted access to land, impacts on customary rights or, more broadly, impacts on their livelihoods. Identified opportunities for Indigenous Peoples to derive shared benefit from any project should aim to address the goals and preferences of the Indigenous Peoples, including improving their standard of living and livelihoods in a culturally appropriate manner, and to foster the long-term sustainability of the natural resources on which they depend.
- Large workforce and history of poor labour and working conditions: Where there are large numbers of workers (including contractors' workers), or geographies where there is a record of child or forced labour in production or supply chains.
- Raw material sourcing: Where sourcing and supply of raw materials may have significant risks and/or impacts (e.g. child or forced labour, revenue transparency, land access or acquisition).
- Manufacturing plants or laboratories which utilise, store or transport Group 3 or Group 4 pathogens (according to the Advisory Committee in Dangerous Pathogens) and / or drug-resistant microbes.
- Transactions/geographies with high business integrity risks.

## 5. Standards, guidelines and other resources

FIs should consult the applicable laws and, as appropriate, international standards such as the IFC Performance Standards and World Bank Group EHS Guidelines. The below focuses on international standards that may be applicable. As stated above in this Guidance Note, FIs shall require their borrowers to comply with applicable laws.

- Applicable IFC Performance Standards

  The IFC Performance Standards most commonly applicable to transactions in this sector are:

- IFC 2012 Performance Standard 1: Assessment and Management of Environmental and Social Risks and Impacts.
- IFC 2012 Performance Standard 2: Labor and Working Conditions.
- IFC 2012 Performance Standard 3: Resource Efficiency and Pollution Prevention.
- IFC 2012 Performance Standard 4: Community Health, Safety and Security.

In addition, other IFC Performance Standards may be applicable depending on the specific characteristics and locations of a company's operations. The screening stage of the FI's E&S DD should always include a routine check for the potential presence of significant impacts covered by IFC Performance Standards.

- Applicable World Bank Group EHS Guidelines
  The most relevant World Bank Group EHS Guidelines in this sector are:
  - World Bank Group General EHS Guidelines.
  - World Bank Group EHS Guidelines for Pharmaceuticals and Biotechnology

- Additional references, standards and guidelines
  Additional resources that may be valuable are:
  - The European Integrated Pollution Prevention and Control Bureau (IPPC) – BAT reference documents (BREFs)
  - ILO's online Encyclopaedia of Occupational Health and Safety
  - Responsible Care
  - Good Manufacturing Practice
  - Council of Europe – Bioethics

- Transparency International Business Principles for Promoting Integrity in the Pharmaceutical Sector.