



Life Sciences

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The challenges facing today's biotechnology and medical device companies are greater than ever. For companies to take promising therapies from the laboratory to the market, they must protect those therapies from IP, regulatory and reputational risks. Furthermore, the last few years have seen increasing pressure from many sides: demand for greater shareholder return, loss of key revenue streams due to patent expiration or generic challenges, fierce competition in key therapeutic areas, pricing pressures from health care payors, increased government regulation beyond core safety issues, rising costs of R&D, challenges in maximizing return in emerging markets and aggressive government enforcement action.

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DLA Piper's team includes award-winning lawyers practicing litigation, compliance and investigations, IP strategy and enforcement, M&A, licensing and distribution and clinical trial advice. They also support clients across all other areas needed to address risk, including government affairs, environmental law, import/export, tax, real estate and employment law. Many of our lawyers are former sector professionals, many have PhDs or other advanced degrees in the life sciences field and others are former government officials or prosecutors.

Recognizing that our clients' needs vary, we rapidly organize and customize our client service teams, whether for a large pharmaceutical company, a mid-sized medical device client or a development-stage biotech company. These teams are supported by international and local practitioners to efficiently meet the demands of the matter.

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- Antitrust and Competition
- Corporate
- Employment
- Intellectual Property and Technology
- International Tax Counsel
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- Real Estate
- Tax
- Corporate Disputes

- Helping sell or acquire a major business asset
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Patent eligibility of diagnostic methods in Australia confirmed: *Ariosa Diagnostics, Inc v Sequenom, Inc* [2021] FCAFC 101

29 June 2021

For many years, the following question awaited judicial determination under Australian law: is a DNA-based diagnostic method patent eligible subject matter? The Full Court of the Federal Court of Australia has confirmed that diagnostic methods involving the practical application of "natural phenomena" can be patentable inventions in Australia.

The Pharmaceutical Corner

June 2021

We look at the underlying decision in *Immunex v. Sandoz* and the potential implications on pharma patent licensing strategies.

Global M&A Intelligence Report 2021

23 June 2021

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Multi-jurisdiction guide for screening foreign investments

26 May 2021

The aim of this guide is not to substitute proper due diligence and specialized advice when conducting business, it will hopefully help the reader navigate the different FDI regimes. Particularly in this complex context and in view of the proliferation of new regimes, by explaining the key aspects of regimes including main issues to consider, thresholds and proceedings to take into consideration when investing in our globalized world.

Israel Group News May 2021

1 May 2021

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The Pharmaceutical Corner

30 March 2021

The opinion may render functional claiming more difficult, but functional claims that follow its guidance may still have an important role to play in pharmaceutical patents.

Understanding the USPTO guidance on patenting AI technologies

30 March 2021

The USPTO guidance opens the door for applicants to obtain patent protection for their AI technologies.

United States imposes significant new export controls and sanctions on Russia and China

23 March 2021

Reflecting a further hardening of US foreign policy and national security policy positions with those two countries.

Corruption Perceptions Index 2020 - a regional perspective

11 February 2021

Last week Transparency International launched the 2020 edition of its Corruption Perceptions Index (CPI), which ranks 180 countries and territories by their perceived levels of public sector corruption, according to experts and business people, using a scale of zero to 100 (100 being very clean and zero being highly corrupt).

The Qualified Maquiladora Approach Agreement has been renewed: Implications for multinationals' transfer pricing

26 January 2021

US-based multinationals using the maquiladora structure to manufacture goods in Mexico are taking note.

Israel Group News January 2021

19 January 2021

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Boardroom Brexit: What the deal means for trade in goods

31 December 2020

BOARDROOM BREXIT

What will the Trade and Cooperation Agreement mean for tariffs and quotas, rules of origin, technical barriers to trade, customs and product standards

Boardroom Brexit: What the deal means for trade in services

31 December 2020

BOARDROOM BREXIT

The TCA has substantial sectoral coverage, including professional and business services (e.g. legal, auditing, architectural services), delivery and telecommunication services, computer-related and digital services, financial services, research and development services, most transport services and environmental services.

The Pharmaceutical Corner

22 December 2020

A precedential decision with potentially far-reaching impacts for future Hatch-Waxman litigation and generic-product launches.

Telehealth around the world: A global guide

19 November 2020

This Global Guide provides an overview of the current state of telehealth regulations worldwide and assists readers to identify the opportunities, challenges and risks, on a country-by-country basis.

Coronavirus: Directors' duties and making decisions in a crisis

2 November 2020

Directors need to carefully consider how to address the risks of the ongoing COVID-19 pandemic within their business, given its impact on the global economy. As many companies are continuing to face significant, and increasing, cash flow pressure, directors should carefully consider their actions in the context of the legal framework.

China signs off on PRC Biosecurity Law: What this means for industry players in China

21 October 2020

The Biosecurity Law establishes a comprehensive framework replacing the current somewhat piecemeal legislation.

China Enforces Tax Collection on Employees Working for Chinese-invested Enterprises Overseas

16 October 2020

With the recent IIT reform in 2019, and the introduction of a number of implementation rules (particularly the tax policy on overseas income), it appears the China tax authorities are taking a harder stance on how overseas income derived by China tax residents will be taxed in China, starting with Chinese expatriates working for Chinese state-owned enterprises.

COVID-19 – Galvanising your business against supply chain and customer insolvency risk

7 October 2020

The risk of unforeseen counterparty customer or supplier financial distress and failure amidst the on-going challenges for businesses from COVID-19 means that pre-emptive legal and operational protections against the risk of heavy financial loss or business disruption from customer/supplier failure are more valuable than ever.

Israel Group News October 2020

7 October 2020

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Mass layoffs and collective redundancies guide

6 October 2020

As COVID-19 continues to impact the global economy in unprecedented ways, companies that have had to scale back or shut down operations are bracing for what the next few months will bring, and what this means for their workforces. In this guide, we examine key considerations for employers looking to make permanent reductions in force across APAC.

Coronavirus Resource Center: Our global repository of insights and events

30 September 2020

A central repository for our reports and commentary on the legal and regulatory concerns arising from the pandemic.

New CFIUS regulations change mandatory filing requirements and increase the importance of US export controls

30 September 2020

The new rule modifies the criteria that trigger a mandatory filing with CFIUS, potentially subjecting more transactions to mandatory CFIUS review.

Philadelphia grows privacy capabilities with a new arrival

30 September 2020

Ronald Plesco, an internationally known information security and privacy lawyer, has joined our Philadelphia office.

The Pharmaceutical Corner

30 September 2020

In this inaugural column, we look at the implications of IPR and PGR proceedings in Hatch Waxman litigation.

Digital Therapeutics - evolution and entry into mainstream healthcare

18 September 2020

Research undertaken by DLA Piper's Life Sciences sector in conjunction with The Lawyer seeks to understand the current developments in the field of digital therapeutics, looking at key questions that need to be addressed if these products are to become mainstream components of health systems across the world.

Human rights compliance programmes in the Life Sciences sector

10 September 2020

The risk of adverse environmental, social or human rights impacts is one that Life Sciences businesses will be familiar with.

Human rights compliance programmes: Why now?

10 September 2020

Businesses are increasingly required to identify and manage their involvement in adverse environmental and social impacts throughout their organisations and supply chains. Previously, drivers for developing human rights compliance programmes have included reputation risk and compliance with best practice and "soft law" standards.

Details of the second tranche of Hong Kong's Employment Support Scheme released

24 August 2020

On 18 August 2020 the Hong Kong government announced details surrounding the second tranche of the Employment Support Scheme. While the majority of the rules surrounding the second tranche remain largely the same as the first tranche, there are new penalties for employers who have fallen foul of a number of nebulous terms.

Release of exposure draft legislation for major reforms to Australia's Foreign Investment Framework

10 August 2020

Many governments around the world have been strengthening their laws relating to foreign investment. Australia is no exception to this development and has just released proposed sweeping reforms to its foreign investment regime. In this article, we provide a high level overview of the key proposed amendments and our thoughts on how some of those proposals are likely to affect foreign investment into Australia.

Vlog series: How to raise equity capital during the Coronavirus pandemic (UK)

4 August 2020

The first half of 2020 has seen an unprecedented volume of activity by companies raising capital through follow-on equity offerings on the London Stock Exchange in response to the Coronavirus pandemic. There have been over 140 equity issues on the London Stock Exchange's main market or AIM since 20 March 2020 raising more than GBP14 billion.

Hong Kong Government increases statutory entitlement for maternity leave

16 July 2020

On 10 October 2018, the Chief Executive stated in her policy address that the government proposed to increase the statutory maternity leave entitlement from ten to 14 weeks.

Israel Group News July 2020

8 July 2020

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PFAS: in California, regulators put cleanup levels on hold, but announce major data hunt

7 MAR 2019

This data hunt will affect thousands of facilities, drinking water systems and private drinking water well owners.

Intellectual Property and Technology News (United States), Issue 23, Q3 2014

10 SEP 2014

INTELLECTUAL PROPERTY AND TECHNOLOGY NEWS

Our Intellectual Property and Technology News reports on worldwide developments in IP and technology law, offering perspectives, analysis and visionary ideas.

Distributing patent rights between affiliates: guidelines to support enforcement rights around the world

16 NOV 2015

Considering a few issues at the outset when rights are distributed between Parent and Affiliate (or between multiple affiliates) may avoid difficulties in the future when a company wants to enforce patent rights.

EVENTS

Previous

Using AI to monitor your compliance risks

31 March 2022
Webinar

Embracing Digital Evolution

15 September 2021
Webinar

EDPB recommendations for safeguarding data transfers after Schrems II

19 November 2020
Webinar

Planning for an Uncertain World

16 November 2020
[TECHLAW EVENT SERIES](#)

Webinar

TechLaw

31 July 2020
[TECHLAW EVENT SERIES](#)

Webinar

NEWS

DLA Piper advises Philip Morris International Inc. on USD16 billion recommended cash offer for Swedish Match

12 May 2022

DLA Piper, as International Counsel, is advising Philip Morris Holland Holdings B.V., an Affiliate of Philip Morris International Inc. (PMI), on its USD16 billion recommended public offer to the shareholders of Swedish Match AB (Swedish Match), a public limited company with shares listed on Nasdaq Stockholm.

DLA Piper advises Poland's Copernicus on its sale to Nemera

29 October 2020

DLA Piper has advised Copernicus, regarded as one of the most valued innovative companies in the Polish health sector, and its founders on its sale to Nemera, a world leader in the design, development and manufacturing of drug delivery devices for the pharmaceutical, biotechnology and generics industries.

Sustainability and ESG

Sustainability and resilience are core business issues in the life sciences sector, given the sector's central role in addressing systemic global challenges including pandemics, access to medicine, and fundamental human rights. Although the specific factors from a sustainability, environmental, social and governance (ESG) perspective in the life science industry differ from those of other industries, creating new and sustainable value in the life science space will depend upon how companies address relevant ESG risks. Boards must actively identify such ESG risks and ensure that they are efficiently mitigated in order for their companies to avoid pitfalls and ensure compliance with evolving regulation around the globe – and also to maintain their competitive position and profitability.

On the basis of our experience in the sector, we believe the following sustainability-related themes to be the core ESG issues that will continue to affect life science businesses:

- **Access and affordability:** Addressing unmet healthcare needs, increasing access to affordable essential medicines and strengthening health systems around the world are all fundamental to social and economic progress. The coronavirus disease 2019 (COVID-19) has further highlighted the importance of the life sciences sector in addressing these challenges. Against this background, international life science business will need to engage in discussions about and develop strategies addressing these issues across the world, particularly with regard to improving the situation in lesser developed countries.
- **Supply chain compliance:** Many governments and regulators around the world are implementing tighter rules on supply chain compliance. To retain their license to operate, life sciences companies must adhere to an evolving set of global laws and regulations. Furthermore, transparency requirements, as well as responsibility and liability for global suppliers are increasing. This ongoing regulatory shift, and the increased likelihood of litigation which goes with it, will have a significant impact on the global life sciences industry. This is because supply chains are often particularly lengthy and complex and influenced by many different internal and external factors that are hard to monitor and control.
- **Product safety and quality:** Fake or substandard medicines lead to hundreds of thousands of deaths each year. Drug safety, along with protecting health consumers from counterfeit medicines and drug diversion, are integral to ensuring public health and maintaining trust and confidence in the life sciences sector. Consequently, life science companies will need to put increasing focus on ensuring product safety as well as maintaining secure distribution channels to patients.
- **Business ethics:** There is increasing stakeholder attention, including from regulators and policymakers and also from providers of capital, on transparency and ethics in business dealings with healthcare providers and medical practitioners for the sale and use of products, as well as in relation to lobbying and advocacy activities. The way in which businesses respond to these expectations can have a direct impact upon their reputation, their cost of capital and ultimately upon their license to operate.
- **Transparency and access in clinical trials:** Stakeholders increasingly expect transparency in clinical trials and wider access to trial data for scientific exchange and research. There is a bright spotlight on participant safety and privacy. Businesses are demanding more effective information sharing to enable informed decision-making and consent, along with post-trial access to results. Technology and collaborative partnerships with patient and health worker groups enable wider representative demographic populations to participate in clinical trials.
- **Sustainable sourcing, product lifecycles and a circular economy:** Markets demand greater visibility across product lifecycles, businesses make commitments to net-zero decarbonisation and business model innovation is driven by circular economy concepts. Underpinned by an increasingly complex transnational regulatory landscape, these developments are changing the way raw materials are sourced; how products are designed, manufactured, packaged, sold, reused or recycled; how waste and hazardous material is treated; and how wider environmental and social impacts relating to issues like emissions, plastics, water use, biodiversity loss, labour conditions and community impacts are managed.
- **Net-zero decarbonisation and optimisation of processes:** In striving to decarbonise the economy, businesses are implementing commitments to Science Based Targets, increasing energy efficiency and reducing carbon output, decreasing dependency on fossil fuels and increasing the use of renewables. The implementation of these initiatives is creating operational efficiencies, optimising the drug manufacturing, packaging and distribution process and reducing costs across the sector.

To discuss the implications of these issues for your business, please contact our ESG leaders.



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Patent eligibility of diagnostic methods in Australia confirmed: *Ariosa Diagnostics, Inc v Sequenom, Inc* [2021] FCAFC 101

29 June 2021

For many years, the following question awaited judicial determination under Australian law: is a DNA-based diagnostic method patent eligible subject matter? The Full Court of the Federal Court of Australia has confirmed that diagnostic methods involving the practical application of “natural phenomena” can be patentable inventions in Australia.

The Pharmaceutical Corner

June 2021

We look at the underlying decision in *Immunex v. Sandoz* and the potential implications on pharma patent licensing strategies.

Global M&A Intelligence Report 2021

23 June 2021

Our annual Global M&A Intelligence Report is based on an analysis of key deal terms in over 3,200 private M&A transactions on which we advised since 2015.

Multi-jurisdiction guide for screening foreign investments

26 May 2021

The aim of this guide is not to substitute proper due diligence and specialized advice when conducting business, it will hopefully help the reader navigate the different FDI regimes. Particularly in this complex context and in view of the proliferation of new regimes, by explaining the key aspects of regimes including main issues to consider, thresholds and proceedings to take into consideration when investing in our globalized world.

Israel Group News May 2021

1 May 2021

ISRAEL GROUP NEWS

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The Pharmaceutical Corner

30 March 2021

The opinion may render functional claiming more difficult, but functional claims that follow its guidance may still have an important role to play in pharmaceutical patents.

Understanding the USPTO guidance on patenting AI technologies

30 March 2021

The USPTO guidance opens the door for applicants to obtain patent protection for their AI technologies.

United States imposes significant new export controls and sanctions on Russia and China

23 March 2021

Reflecting a further hardening of US foreign policy and national security policy positions with those two countries.

Corruption Perceptions Index 2020 - a regional perspective

11 February 2021

Last week Transparency International launched the 2020 edition of its Corruption Perceptions Index (CPI), which ranks 180 countries and territories by their perceived levels of public sector corruption, according to experts and business people, using a scale of zero to 100 (100 being very clean and zero being highly corrupt).

The Qualified Maquiladora Approach Agreement has been renewed: Implications for multinationals' transfer pricing

26 January 2021

US-based multinationals using the maquiladora structure to manufacture goods in Mexico are taking note.

Israel Group News January 2021

19 January 2021

ISRAEL GROUP NEWS

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Boardroom Brexit: What the deal means for trade in goods

31 December 2020

BOARDROOM BREXIT

What will the Trade and Cooperation Agreement mean for tariffs and quotas, rules of origin, technical barriers to trade, customs and product standards

Boardroom Brexit: What the deal means for trade in services

31 December 2020

BOARDROOM BREXIT

The TCA has substantial sectoral coverage, including professional and business services (e.g. legal, auditing, architectural services), delivery and telecommunication services, computer-related and digital services, financial services, research and development services, most transport services and environmental services.

The Pharmaceutical Corner

22 December 2020

A precedential decision with potentially far-reaching impacts for future Hatch-Waxman litigation and generic-product launches.

Telehealth around the world: A global guide

19 November 2020

This Global Guide provides an overview of the current state of telehealth regulations worldwide and assists readers to identify the opportunities, challenges and risks, on a country-by-country basis.

Coronavirus: Directors' duties and making decisions in a crisis

2 November 2020

Directors need to carefully consider how to address the risks of the ongoing COVID-19 pandemic within their business, given its impact on the global economy. As many companies are continuing to face significant, and increasing, cash flow pressure, directors should carefully consider their actions in the context of the legal framework.

China signs off on PRC Biosecurity Law: What this means for industry players in China

21 October 2020

The Biosecurity Law establishes a comprehensive framework replacing the current somewhat piecemeal legislation.

China Enforces Tax Collection on Employees Working for Chinese-invested Enterprises Overseas

16 October 2020

With the recent IIT reform in 2019, and the introduction of a number of implementation rules (particularly the tax policy on overseas income), it appears the China tax authorities are taking a harder stance on how overseas income derived by China tax residents will be taxed in China, starting with Chinese expatriates working for Chinese state-owned enterprises.

COVID-19 – Galvanising your business against supply chain and customer insolvency risk

7 October 2020

The risk of unforeseen counterparty customer or supplier financial distress and failure amidst the on-going challenges for businesses from COVID-19 means that pre-emptive legal and operational protections against the risk of heavy financial loss or business disruption from customer/supplier failure are more valuable than ever.

Israel Group News October 2020

7 October 2020

ISRAEL GROUP NEWS

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Mass layoffs and collective redundancies guide

6 October 2020

As COVID-19 continues to impact the global economy in unprecedented ways, companies that have had to scale back or shut down operations are bracing for what the next few months will bring, and what this means for their workforces. In this guide, we examine key considerations for employers looking to make permanent reductions in force across APAC.

Coronavirus Resource Center: Our global repository of insights and events

30 September 2020

A central repository for our reports and commentary on the legal and regulatory concerns arising from the pandemic.

New CFIUS regulations change mandatory filing requirements and increase the importance of US export controls

30 September 2020

The new rule modifies the criteria that trigger a mandatory filing with CFIUS, potentially subjecting more transactions to mandatory CFIUS review.

Philadelphia grows privacy capabilities with a new arrival

30 September 2020

Ronald Plesco, an internationally known information security and privacy lawyer, has joined our Philadelphia office.

The Pharmaceutical Corner

30 September 2020

In this inaugural column, we look at the implications of IPR and PGR proceedings in Hatch Waxman litigation.

Digital Therapeutics - evolution and entry into mainstream healthcare

18 September 2020

Research undertaken by DLA Piper's Life Sciences sector in conjunction with The Lawyer seeks to understand the current developments in the field of digital therapeutics, looking at key questions that need to be addressed if these products are to become mainstream components of health systems across the world.

Human rights compliance programmes in the Life Sciences sector

10 September 2020

The risk of adverse environmental, social or human rights impacts is one that Life Sciences businesses will be familiar with.

Human rights compliance programmes: Why now?

10 September 2020

Businesses are increasingly required to identify and manage their involvement in adverse environmental and social impacts throughout their organisations and supply chains. Previously, drivers for developing human rights compliance programmes have included reputation risk and compliance with best practice and "soft law" standards.

Details of the second tranche of Hong Kong's Employment Support Scheme released

24 August 2020

On 18 August 2020 the Hong Kong government announced details surrounding the second tranche of the Employment Support Scheme. While the majority of the rules surrounding the second tranche remain largely the same as the first tranche, there are new penalties for employers who have fallen foul of a number of nebulous terms.

Release of exposure draft legislation for major reforms to Australia's Foreign Investment Framework

10 August 2020

Many governments around the world have been strengthening their laws relating to foreign investment. Australia is no exception to this development and has just released proposed sweeping reforms to its foreign investment regime. In this article, we provide a high level overview of the key proposed amendments and our thoughts on how some of those proposals are likely to affect foreign investment into Australia.

Vlog series: How to raise equity capital during the Coronavirus pandemic (UK)

4 August 2020

The first half of 2020 has seen an unprecedented volume of activity by companies raising capital through follow-on equity offerings on the London Stock Exchange in response to the Coronavirus pandemic. There have been over 140 equity issues on the London Stock Exchange's main market or AIM since 20 March 2020 raising more than GBP14 billion.

Hong Kong Government increases statutory entitlement for maternity leave

16 July 2020

On 10 October 2018, the Chief Executive stated in her policy address that the government proposed to increase the statutory maternity leave entitlement from ten to 14 weeks.

Israel Group News July 2020

8 July 2020

ISRAEL GROUP NEWS

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PFAS: in California, regulators put cleanup levels on hold, but announce major data hunt

7 MAR 2019

This data hunt will affect thousands of facilities, drinking water systems and private drinking water well owners.

Intellectual Property and Technology News (United States), Issue 23, Q3 2014

10 SEP 2014

INTELLECTUAL PROPERTY AND TECHNOLOGY NEWS

Our Intellectual Property and Technology News reports on worldwide developments in IP and technology law, offering perspectives, analysis and visionary ideas.

Distributing patent rights between affiliates: guidelines to support enforcement rights around the world

16 NOV 2015

Considering a few issues at the outset when rights are distributed between Parent and Affiliate (or between multiple affiliates) may avoid difficulties in the future when a company wants to enforce patent rights.

EVENTS

Previous

Using AI to monitor your compliance risks

31 March 2022

Webinar

Embracing Digital Evolution

15 September 2021

Webinar

EDPB recommendations for safeguarding data transfers after Schrems II

19 November 2020
Webinar

Planning for an Uncertain World

16 November 2020
[TECHLAW EVENT SERIES](#)

Webinar

TechLaw

31 July 2020
[TECHLAW EVENT SERIES](#)

Webinar

NEWS

DLA Piper advises Philip Morris International Inc. on USD16 billion recommended cash offer for Swedish Match

12 May 2022

DLA Piper, as International Counsel, is advising Philip Morris Holland Holdings B.V., an Affiliate of Philip Morris International Inc. (PMI), on its USD16 billion recommended public offer to the shareholders of Swedish Match AB (Swedish Match), a public limited company with shares listed on Nasdaq Stockholm.

DLA Piper advises Poland's Copernicus on its sale to Nemera

29 October 2020

DLA Piper has advised Copernicus, regarded as one of the most valued innovative companies in the Polish health sector, and its founders on its sale to Nemera, a world leader in the design, development and manufacturing of drug delivery devices for the pharmaceutical, biotechnology and generics industries.

Sustainability and ESG

Sustainability and resilience are core business issues in the life sciences sector, given the sector's central role in addressing systemic global challenges including pandemics, access to medicine, and fundamental human rights. Although the specific factors from a sustainability, environmental, social and governance (ESG) perspective in the life science industry differ from those of other industries, creating new and sustainable value in the life science space will depend upon how companies address relevant ESG risks. Boards must actively identify such ESG risks and ensure that they are efficiently mitigated in order for their companies to avoid pitfalls and ensure compliance with evolving regulation around the globe – and also to maintain their competitive position and profitability.

On the basis of our experience in the sector, we believe the following sustainability-related themes to be the core ESG issues that will

continue to affect life science businesses:

- **Access and affordability:** Addressing unmet healthcare needs, increasing access to affordable essential medicines and strengthening health systems around the world are all fundamental to social and economic progress. The coronavirus disease 2019 (COVID-19) has further highlighted the importance of the life sciences sector in addressing these challenges. Against this background, international life science business will need to engage in discussions about and develop strategies addressing these issues across the world, particularly with regard to improving the situation in lesser developed countries.
- **Supply chain compliance:** Many governments and regulators around the world are implementing tighter rules on supply chain compliance. To retain their license to operate, life sciences companies must adhere to an evolving set of global laws and regulations. Furthermore, transparency requirements, as well as responsibility and liability for global suppliers are increasing. This ongoing regulatory shift, and the increased likelihood of litigation which goes with it, will have a significant impact on the global life sciences industry. This is because supply chains are often particularly lengthy and complex and influenced by many different internal and external factors that are hard to monitor and control.
- **Product safety and quality:** Fake or substandard medicines lead to hundreds of thousands of deaths each year. Drug safety, along with protecting health consumers from counterfeit medicines and drug diversion, are integral to ensuring public health and maintaining trust and confidence in the life sciences sector. Consequently, life science companies will need to put increasing focus on ensuring product safety as well as maintaining secure distribution channels to patients.
- **Business ethics:** There is increasing stakeholder attention, including from regulators and policymakers and also from providers of capital, on transparency and ethics in business dealings with healthcare providers and medical practitioners for the sale and use of products, as well as in relation to lobbying and advocacy activities. The way in which businesses respond to these expectations can have a direct impact upon their reputation, their cost of capital and ultimately upon their license to operate.
- **Transparency and access in clinical trials:** Stakeholders increasingly expect transparency in clinical trials and wider access to trial data for scientific exchange and research. There is a bright spotlight on participant safety and privacy. Businesses are demanding more effective information sharing to enable informed decision-making and consent, along with post-trial access to results. Technology and collaborative partnerships with patient and health worker groups enable wider representative demographic populations to participate in clinical trials.
- **Sustainable sourcing, product lifecycles and a circular economy:** Markets demand greater visibility across product lifecycles, businesses make commitments to net-zero decarbonisation and business model innovation is driven by circular economy concepts. Underpinned by an increasingly complex transnational regulatory landscape, these developments are changing the way raw materials are sourced; how products are designed, manufactured, packaged, sold, reused or recycled; how waste and hazardous material is treated; and how wider environmental and social impacts relating to issues like emissions, plastics, water use, biodiversity loss, labour conditions and community impacts are managed.
- **Net-zero decarbonisation and optimisation of processes:** In striving to decarbonise the economy, businesses are implementing commitments to Science Based Targets, increasing energy efficiency and reducing carbon output, decreasing dependency on fossil fuels and increasing the use of renewables. The implementation of these initiatives is creating operational efficiencies, optimising the drug manufacturing, packaging and distribution process and reducing costs across the sector.

To discuss the implications of these issues for your business, please contact our ESG leaders.