



Life Sciences

As the legal matters confronting our life science clients are varied, so are the skill sets we employ. DLA Piper's life sciences team comprises lawyers with legal, scientific and medical knowledge who understand the complexity of the business and regulatory environments in which our clients operate.

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.

Our life sciences sector team is one of the largest and most active of any law firm. Operating as one team across more than 30 jurisdictions, we combine subject matter experience with considerable knowledge of the sector, including the scientific, medical, regulatory, commercial and enforcement environments facing our biopharmaceutical, medical device, research and diagnostics clients.

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.

Our cutting-edge staffing, budgeting and billing systems, created specifically to assist our global life science clients, ensure that our teams deliver value in addition to great results.

Our life sciences team helps clients solve their biggest challenges every day. Examples of our experience include:

- Conducting a sensitive investigation in China
- Negotiating a complex multi-country distribution deal in Latin America
- Acting as National Counsel on a mass tort in the US

Marco de Morpurgo

Partner
Rome
T: +39 06 68 880 1
marco.demorpurgo@dlapiper.com

Andrew P. Gilbert

Partner
New Jersey (Short Hills)
T: +1 973 520 2553
andrew.gilbert@dlapiper.com

Matt Holian

Partner
Boston
T: +1 617 406 6009
matt.holian@dlapiper.com

- Antitrust and Competition
- Corporate
- Employment
- Intellectual Property and Technology
- International Tax Counsel
- Litigation, Arbitration and Investigations
- Real Estate
- Tax

- Helping sell or acquire a major business asset
- Advising on implementation of transparency laws or the impact of other new legislation
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INSIGHTS

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30 June 2022

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Boardroom Brexit: What the deal means for business

31 December 2020

[BOARDROOM BREXIT](#)

Welcome to this last edition of Boardroom Brexit, marking the end of the negotiations and the agreement of a new trade deal, the UK-EU Trade and Cooperation Agreement (TCA). In this edition, we summarise the impact of the deal on all aspects of business operations in one place – please use the hyperlinks below to help you navigate the report.

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.

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.

Germany's New Foreign Direct Investments (FDI) Act took effect on 11 October 2020

19 October 2020

In addition to the intended amendments to the Foreign Trade and Payments Act Germany's Federal Government on 20 May 2020 has decided on a bill that broadens the scope and the scrutiny with regard to foreign investments.

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.

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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The legal challenges facing the vaping industry in the EU/UK and the US: An overview and a look ahead

7 July 2020

Notes as the industry matures.

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

Women in Science and Technology Conference

29 October 2020 | 5:30 - 7:30 p.m. AST
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 Linus Health on its acquisition of Kinesis Health Technologies

6 April 2022

DLA Piper has advised Boston-based digital health company Linus Health on its acquisition of Kinesis Health Technologies, a Dublin-based leader in physical function assessment for older adults.

DLA Piper lawyers, practices and sectors ranked in latest edition of *The Legal 500 Latin America*

25 October 2021

DLA Piper today announced that the firm received 46 individual lawyer rankings and 68 firm rankings in The Legal 500 Latin America 2022 guide.

DLA Piper advises Hinduja Global Solutions on USD1.2 billion sale of its healthcare business

11 August 2021

DLA Piper is advising Hinduja Global Solutions Limited (HGS) on the sale of its healthcare solutions business to Baring Private Equity Asia, in a transaction valued at USD1.2 billion subject to closing adjustments.

DLA Piper advises HUTCHMED on its Hong Kong IPO

8 July 2021

DLA Piper is advising global biopharmaceutical company HUTCHMED on its Hong Kong public offering. This will be the third listing for the company, following its first on London's AIM exchange and then NASDAQ in the US.

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 (SESG) 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 SESG risks. Boards must actively identify such SESG 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 SESG 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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Israel Group News January 2021

19 January 2021

[ISRAEL GROUP NEWS](#)

In this issue, our global activities, latest publications, recent events and more.

Boardroom Brexit: What the deal means for business

31 December 2020

[BOARDROOM BREXIT](#)

Welcome to this last edition of Boardroom Brexit, marking the end of the negotiations and the agreement of a new trade deal, the UK-EU Trade and Cooperation Agreement (TCA). In this edition, we summarise the impact of the deal on all aspects of business operations in one place – please use the hyperlinks below to help you navigate the report.

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.

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.

Germany's New Foreign Direct Investments (FDI) Act took effect on 11 October 2020

19 October 2020

In addition to the intended amendments to the Foreign Trade and Payments Act Germany's Federal Government on 20 May 2020 has decided on a bill that broadens the scope and the scrutiny with regard to foreign investments.

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.

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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The legal challenges facing the vaping industry in the EU/UK and the US: An overview and a look ahead

7 July 2020

Notes as the industry matures.

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

Women in Science and Technology Conference

29 October 2020 | 5:30 - 7:30 p.m. AST

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 Linus Health on its acquisition of Kinesis Health Technologies

6 April 2022

DLA Piper has advised Boston-based digital health company Linus Health on its acquisition of Kinesis Health Technologies, a Dublin-based leader in physical function assessment for older adults.

DLA Piper lawyers, practices and sectors ranked in latest edition of *The Legal 500 Latin America*

25 October 2021

DLA Piper today announced that the firm received 46 individual lawyer rankings and 68 firm rankings in The Legal 500 Latin America 2022 guide.

DLA Piper advises Hinduja Global Solutions on USD1.2 billion sale of its healthcare business

11 August 2021

DLA Piper is advising Hinduja Global Solutions Limited (HGS) on the sale of its healthcare solutions business to Baring Private Equity Asia, in a transaction valued at USD1.2 billion subject to closing adjustments.

DLA Piper advises HUTCHMED on its Hong Kong IPO

8 July 2021

DLA Piper is advising global biopharmaceutical company HUTCHMED on its Hong Kong public offering. This will be the third listing for the company, following its first on London's AIM exchange and then NASDAQ in the US.

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