LIFE SCIENCES: 2023 TRENDS

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We anticipate a year of reserved optimism in the life sciences industry for 2023. Despite uncertain financial markets and pricing challenges in the US, we expect an increase in transactional activity, with a continued focus on strategic divestiture, MedTech, and reliance on licensing and collaboration. At the same time, the level of regulatory pressure on the life sciences industry will cause headwinds, with shifting regulatory conditions and multiple pressure points across antitrust, ESG, employment and tax presenting attendant enforcement and litigation risks.

1. Biopharma Transactions

In 2022, several factors impacted life sciences transactional activity. The market for biotech financing was generally considered to be dismal, both for venture capital and the public capital markets. Pre-commercial biotechs continued to burn cash and, in the face of these challenges, many resorted to layoffs and deprioritisation of pipeline programmes; a fair number closed their doors altogether. With a few exceptions, notably the recently announced acquisition of Horizon Therapeutics by Amgen, we saw no large-scale M&A.

Slow but Steady Uptick in M&A

While we anticipated more big pharma/biotech M&A activity, we did not see a material increase from 2021, as buyers and sellers struggled to reach alignment on value given the dramatic decrease in biotech valuations from 2021 to 2022. However, for 2023, indications are that we will see an uptick in M&A. Big pharmas have cash and are focused on upcoming revenue gaps from patent expirations. Biotechs continue to burn cash with no improvement in financing conditions on the immediate horizon. Creative deal makers will find ways to bridge gaps on valuations, such as use of milestone payments or contingent value rights. While larger deals are always possible, as is traditionally the case, at the JPMorgan Healthcare Conference in January 2023, big pharma CEOs generally focused on bolt-on deals.[1]

Financing

We expect continued challenges in the financing markets, at least in the first half of the year. Word during JPMorgan was that only companies with late-stage assets in attractive therapeutic areas were garnering significant interest from new investors. Venture capital funds, despite having raised significant funds in recent years, remain cautious and focused on shoring up existing portfolio companies. However, there seemed to be a general view that at some point, these funds will need to put their capital to work. One positive for the market has been private equity's increased investment in life sciences, which is expected to continue this year. On this front, Blackstone has been leading the way, having made ten investments out of a $4.6 billion life sciences fund launched in 2020. With the 2022 passage of the Inflation Reduction Act in the US, we expect that acquirors and in-licensors will begin revising their financial models to accommodate the potential impact of a future Medicaid/Medicare price negotiation.[2]

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1) For our conference highlights, see: https://blog.freshfields.us/post/102i5wf/2023-j-p-morgan-healthcare-conference-highlights.

2) See further: https://blog.freshfields.us/post/102i6ic/the-drug-pricing-landscape-in-2023-renewed-pressure-for-pricing-reform.

We expect that this, in turn, will have an immediate adverse impact on deal economics, particularly in small molecule deals.

Continued Reliance on Licensing and Collaboration

As companies search for flexible and creative ways to access funding and novel technologies, we expect to see continued reliance on licensing and collaboration deals. This is particularly true given the challenges in financing larger-scale clinical trials and biotechs looking to monetise lower priority pipeline programmes.

Divestitures and Spin-offs

Big pharmas continue to pursue large-scale spin-off transactions such as the spin-offs by GSK and J&J of their consumer health businesses and Novartis' publicly announced spin-off of its generics business, Sandoz. We would expect big pharma companies to continue to review their businesses and product portfolios and look to pare assets which do not align with long-term strategic objectives.

2. MedTech

In 2022 there was a strong appetite for MedTech investment by private equity firms and other financial sponsors, as well as increased strategic collaborations and partnerships among MedTech companies. These trends are expected to continue as the accelerated acceptance of virtual care and demographic trends such as an aging population, increasing chronic illnesses and healthcare worker shortages sustain demand for MedTech-enabled solutions.

At the same time, we expect some headwinds with continued intense scrutiny by global antitrust and competition authorities, and with other regulators exercising caution as the sector continues to grapple with data privacy, security and other key MedTech regulatory issues. In particular, we are tracking women's health-focused companies, seeking to expand their telemedicine services in the aftermath of the overturning of *Roe v Wade*, as well as companies with AI and advanced technology offerings seeking guidance on applicable regulatory frameworks. For more information, see our Ten Key MedTech Themes for 2023.[3]

3. Antitrust

We expect the antitrust enforcement spotlight to remain trained on life sciences transactions, including MedTech, in 2023. We expect global antitrust regulators to continue to push jurisdictional boundaries and expand their powers to catch perceived 'killer' acquisitions (building on examples such as *Illumina/Grail*), pursue novel theories of harm (especially in the context of data and technology driven acquisitions) and to scrutinise conduct more broadly, with updated Merger Guidelines anticipated in the US aimed at modernising enforcement, including in relation to novel issues such as labour market considerations and innovation. For example, Senator Elizabeth Warren of Massachusetts recently called upon the FTC to closely scrutinise pharma mergers, expressing concern over 'rampant consolidation in the pharmaceutical industry'.

In the context of licensing and collaboration, we anticipate information exchange to remain a hot topic. In summer 2023 we expect to see new EU block exemption regulations on R&D and specialisation agreements, as well as updated guidance on horizontal cooperation agreements come into force. Although the revisions helpfully recognise a broader range of collaboration structures, particularly in the context of the R&D block exemption, the current draft guidance does appear to lower the bar for potential unlawful information exchange and authorities continue to monitor closely for competition breaches concerning information exchange between actual or potential competitors. These concerns also come into focus as part of the recent crackdown on interlocking directorships

3) https://technologyquotient.freshfields.com/post/102i4hu/10-key-medtech-themes-for-2023.

and shared ownership. Where collaboration partners are actual or potential competitors, they should be mindful of who sits on collaboration committees/boards and carefully monitor the substantive risk and safeguards. The DOJ/FTC Antitrust Guidelines for Collaborations Among Competitors specifically note that appropriate safeguards governing information sharing make it less likely that collaboration will raise antitrust concerns.[4]

4. IP and Patents

In Europe, 2023 brings a major change in the patent enforcement landscape. After (literally) decades of negotiations, and more recent delays, 1 June 2023 will see the opening of the Unified Patent Court, a single court offering remedies in a single decision for infringement and validity covering 17 EU Member States at its opening (with scope to expand to all EU Member States). As the system will initially run in parallel with national courts, patentees are currently deciding which of their patents to 'opt out' of the new system. Although many have speculated that big pharma will opt out wholesale, we expect that the most sophisticated companies will have made strategic choices allowing them to road test the new court and contribute to the early cases which will refine its procedures.

We expect continued focus on the question of how much information a patent must disclose to the reader. The US Supreme Court is due to consider in *Amgen v. Sanofi* the Federal Circuit's requirement that the disclosure of a patent specification must enable the reader to 'reach-the-full-scope' of the claims without undue experimentation. In addition, the EPO's senior tribunal (the Enlarged Board of Appeal) is due to give its decision on the related question of how much information a patent must include to make the claims 'plausible'. Both cases are of fundamental importance to the life sciences sector, as we expect them to redraw the line as to when, for example, a patent to a new class of molecules can be filed, based on the amount of data needed to support that filing. These are critical questions where patents are crucial to value in a competitive research environment.

5. The Regulatory Space

In the EU, there is major legislative change on the agenda, in particular in the health data and product liability arenas. In the UK, regulatory uncertainty remains the watchword post-Brexit, and we are yet to see concrete regulatory reform, with significant updates expected for medical devices and clinical trial regulation. Health data will remain a key topic.

In the EU, three key data-focused EU enactments move towards ratification: first, the European Health Data Space Regulation,[5] which aims to facilitate the use of health data including for secondary purposes such as research or innovation.[6] Second, the AI Act, which aims to provide a secure legal framework for the use of AI,[7] a particular challenge in the health space due to GDPR. The scope of this regulation and the classification of 'high risk AI' will continue to be the subject of intense debate between lawmakers. Third, the proposed Data Act (of particular interest for medical devices manufacturers) will allow broader sharing of data collected by products to facilitate research and innovation. The interplay of these proposed regulations with each other and with existing frameworks (such as GDPR and the Medical Devices Regulation (MDR)) remains to be seen. In the UK, health data and unlocking health datasets, including those of the NHS, remains a UK government priority, but faces significant interoperability, cybersecurity and data privacy concerns.

Significantly, the EU published draft legislation to create a more claimant-friendly EU product liability regime in September 2022. The new EU Product Liability Directive and AI Liability Directive will have far-reaching implications for the life sciences industry if they are passed.[8]

4) For further predictions for global antitrust in 2023 see: https://www.freshfields.com/en-gb/our-thinking/our-podcasts/risk-and-compliance-podcast/essential-antitrust-25-antitrust-in-2023-10-key-themes---growing-unpredictability-and-brand-new-enforcement-tools/.

5) https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space_en.

6) https://technologyquotient.freshfields.com/post/102ho8u/making-the-most-of-health-data-commission-publishes-proposal-for-a-european-heal.

7) https://www.freshfields.de/our-thinking/campaigns/technology-quotient/tech-and-platform-regulation/artificial-intelligence-regulation/the-eus-proposed-ai-regulation/.

8) See further: https://riskandcompliance.freshfields.com/post/102i2zv/the-proposed-revised-product-liability-directive-implications-for-life-sciences; and https://technologyquotient.freshfields.com/post/102hy5z/new-ai-liability-regime-unveiled-by-the-european-commission.

The EU Parliament has recently adopted legislation that extends the transition period provided for in the MDR (until 2027 or 2028, depending on the risk class) in light of serious capacity issues of notified bodies threatening device availability. In the UK, similarly, there has been some recent reprieve for the industry with the extension or expansion of certain transitional provisions and international recognition procedures (including with respect to product conformity marking).

Finally, we note that, building on the EU Pharmaceutical Strategy published in 2020,[9] the European Commission has launched several public consultations in the life sciences sector. Following a 2021 consultation,[10] the European Commission will publish its proposal for a comprehensive reform of the EU general pharmaceuticals legislation in March 2023; this will aim to build a 'future-proof' and 'crisis-resistant' medicines regulatory system by fostering innovation (including in areas of unmet medical need), improving security of supply, adapting to new scientific and technological developments and reducing red tape. It appears that measures like the reduction of the regulatory data protection period, facilitated procedures for the authorisation of generics and biosimilars, and measures to promote the development of antimicrobials or the reduction of regulatory burden are being discussed. The proposal will further include a revision of the specific legislation on orphan drugs and paediatric medicine, which will address both the level of government support for product development in areas where the need for medicines is greatest and incentives to encourage the development of medicines for rare diseases.

In the US, we expect to see the FDA provide fuller guidance[11] regarding medical devices that use AI, machine learning, and other advanced technologies, as well as those governing the remote management of clinical trials. We also anticipate that US lawmakers and other stakeholder groups will continue to push the Department of Health and Human Services to use their powers to lower the price of certain therapeutics.

6. ESG

ESG issues are well-established boardroom concerns. We have highlighted three areas to watch in the sector for 2023: the impact of business operations (including value chains) on biodiversity in the wake of COP15; issues related to pharmaceuticals in the environment; and a continuing focus on climate change.

In 2022 there was increasing attention paid to biodiversity issues generally, which are felt acutely in the sector given its dependency on the natural environment. Much like the 'Paris moment' for climate change, the outcomes of COP15[12] last December are expected to act as a landmark moment for biodiversity and will influence how businesses, governments and the healthcare industry address biodiversity decline in the next decade. The industry should monitor closely the Taskforce on Nature-related Financial Disclosure recommendations (expected in September), given the Taskforce's designation of the sector as a 'priority'. We have also previously discussed the growing importance to the industry of new obligations in Europe to ensure deforestation-free supply chains.[13]

The topic of pharmaceuticals in the environment is not new, but this year we expect more intense focus in light of rapidly developing science, pressure from investors, and important regulatory developments (such as the inclusion of several APIs on the priority substance list for EU water legislation and proposed bans on relevant PFAS, as well as a focus on greenwashing (see below)).

The industry faces particular obstacles to achieving more rapid progress in decarbonisation and climate change and greenhouse gas reduction efforts (noting significant recent

9) https://health.ec.europa.eu/medicinal-products/pharmaceutical-strategy-europe_en.

10) https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12963-Revision-of-the-EU-general-pharmaceuticals-legislation_en.

11) https://technologyquotient.freshfields.com/post/102i4hu/10-key-medtech-themes-for-2023.

12) https://sustainability.freshfields.com/post/102i3n9/cop15-the-importance-of-biodiversity-and-what-it-means-for-your-businesses?share=True.

13) https://sustainability.freshfields.com/post/102i3n9/cop15-the-importance-of-biodiversity-and-what-it-means-for-your-businesses.

ESG commitments[14]). These include: the reliance in healthcare on metered dose inhalers and anaesthetic gases (we note the recent European Commission proposal for a regulation on fluorinated greenhouse gases in this regard); the particular sticky challenges associated with decarbonisation of clinical trials and the R&D phase more generally, especially given the proportion of development products that never make it to market; and the relative carbon intensity of new highly innovative therapeutics (for example, certain advanced biologics and gene therapies), when compared with traditional small molecules.

7. Employment Matters

In the employment arena, we are witnessing a changing and challenging landscape for employers in the sector. Retention of workers and enforcement of post-termination restrictive covenants will be front of mind, but the regulatory and enforcement backdrop is increasingly complex. The US FTC's proposal to effectively ban all non-compete clauses will, if implemented as currently drafted, make it easier for employees to move between competitors. Some may welcome this, but others will worry about the potential impact on valuable confidential information, including in the context of acquisitions where the FTC's proposal would permit non-competes only in limited circumstances.

We also anticipate a surge in collective employee activism. Many life sciences multinationals will of course already have long-standing relationships with employee representatives, but we expect more significant pressure to be exerted by representatives, potentially harnessing the power of technology and social media to gain traction.

Finally, with the implementation of the EU Whistleblowing Directive across Europe, global businesses will continue to face potential operational challenges and conflicting interpretations of the implications for whistleblowing systems and broader compliance obligations. Getting this right will be particularly crucial in the life sciences sector given the criticality of a strong speak-up culture. For more information, see our run-down of 2023 employment developments to look out for.[15]

8. Tax

We expect further progress on international tax reforms in 2023 (with potential enormous significance for larger multinationals), with the OECD and G20 international tax reform project gathering momentum through 2022. The EU finally reached unanimous agreement in December 2022 on a directive implementing the Pillar Two rules (involving a minimum 15 per cent rate for larger multinationals with above a €750 million revenue threshold). We expect that this crucial milestone will encourage a number of other jurisdictions to follow suit, and will also incentivise countries to introduce domestic top-up taxes to hit the minimum 15 per cent rate. In-scope multinationals will face (at a minimum) a heavy compliance burden preparing for implementation of these new rules from 2024. Pillar One involves proposals to reattribute taxable profit to market jurisdictions (applicable only to the very largest multinationals above a €20 billion revenue threshold and 10 per cent profit margin), and progress here has been slower (as anticipated), although the OECD is targeting signature of a multilateral convention in H1, with a view to it entering into force in 2024.

We also anticipate global ongoing scrutiny of the tax treatment of royalty payments. Multinationals with cross-border royalty flows should consider whether the profits taxable in different jurisdictions are commensurate with the value added by the local activities taking place, including whether historic 'transfer pricing' arrangements should be revisited. We expect that tax authorities will also increasingly seek to apply royalty withholding taxes having regard to the substance in relevant jurisdictions, which is likely to lead to more challenges.

14) https://sustainability.freshfields.com/post/102hnfk/climate-change-supply-chains-resource-scarcity-and-other-esg-focus-areas-for-th.

15) http://ssl.freshfields.com/noindex/documents/0123/Employment-incentives-and-pensions-10-things-to-look-out-for-in-2023.pdf.

9. Disputes and Enforcement

Enforcement and dispute risks feature through all of the areas we have highlighted. Regulators continue to have the life sciences sector in their sights, and compliance is not made easier by a lack of regulatory clarity in many areas.

We have generally seen an increase in M&A-related disputes, in particular related to licensing, collaboration and milestones, which will continue in 2023 aligned with M&A trends. On the ESG front, action in respect of supply chains is on the rise and we expect a continued increase in strategically motivated litigation (including shareholder litigation) in respect of sustainability issues designed to influence corporate behaviour (noting increasingly stringent sustainability reporting obligations). Greenwashing remains high on the enforcement agenda, in respect of brand marketing as well as advertising for specific products, with ensuing follow-on litigation risk. More generally, we see an increasing trend of consumer and data privacy litigation. In the EU, for example, we note traditionally US claimant firms entering the fray, as well as continued efforts to use novel procedural mechanisms for collective proceedings. These litigation risks will only increase as the boundaries between traditional tech, pharma and medical devices blur, and as EU Member States introduce domestic legislation to implement the EU Representative Actions Directive (see further here).[16]

Compliance should remain high on the agenda. Enforcement in 2022 continued to highlight the importance of addressing white collar crime risks in an M&A context, both with regard to regulators' expectations for pre-acquisition due diligence as well as implementing reasonable integration measures post-closing to incorporate newly acquired entities into compliance management systems and enhance policies and procedures as appropriate. Criminal and regulatory resolutions with life sciences companies have also included requirements regarding compliance programme design and oversight. At the same time, multiple drivers of white collar enforcement remain a key focus for prosecutors and regulatory agencies, with increasing inter-agency, cross-border cooperation. We expect continuing focus on life science companies' marketing and promotion of medications, as well as their interactions with regulatory agencies and healthcare professionals. And the global focus on sanctions compliance could require very complex analyses of permissible sales and other transactions, given potentially differing exemptions for medicines and medical supplies under different sanctions regimes.

16) See further: https://riskandcompliance.freshfields.com/post/102hy97/a-new-collective-action-regime-in-germany-draft-bill-on-the-implementation-of-t.