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Restructuring and insolvency in the life sciences sector: Q&A

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This Q&A explores the current trends in restructuring and insolvency (R&I) activity in the life sciences sector and considers the sector-specific issues and risks practitioners should be aware of.

For guidance on restructuring and insolvency generally, see the Restructuring & Insolvency practice area.

Overview

1. Have you seen significant restructuring and insolvency (R&I) activity in the life sciences sector in the last 12 months?

The disruption within supply chains, alongside the increase in energy costs and the disruption to medical trials (caused by clinical trials being stopped or delayed due to pandemic-related restrictions in relation to the movement of people or as a result of difficulties with patient recruitment) may lead to an increase in distress and insolvency situations in the sector in the coming months.

Nonetheless, during the course of the last year, the sector saw a strong period of growth, which was fuelled (in part) by the availability of funding, primarily via equity investment. Furthermore, the advancement of technology has led to the increasingly common partnership of life science companies with technology companies.

In addition, the UK had seen historically low insolvency rates from the start of the pandemic up until the end of 2021, which was due in a large part to the unprecedented government support and temporary measures implemented in the Corporate Insolvency and Governance Act 2020 (CIGA). However, with the withdrawal of temporary support measures in 2022, and a reduction of equity investment, the picture is changing, and insolvency rates across industries are picking up.

When considering the life sciences sector, it is important to consider the medicines industry and the medical devices industry separately as the factors relevant to these industries often diverge.

Medicines

During the last 12 months in particular, there has been significant investment in the medicines industry and the number of global IPOs in healthcare is rising significantly. The effects of the pandemic have, in some ways, bolstered the sector. Examples of this include the relaxation of regulations to assist in the development of vaccine and drug treatments for COVID-19 and also the use of telemedicine rather than traditional in-person appointments.

Medical devices

The medical devices industry tends to consist of smaller companies, often without the investment opportunities benefiting the larger medicine companies, and also without the buying power of Big Pharma. As such, these entities tend to be more vulnerable to distress than those companies in the medicines industry.

However, in the last 12 months, in addition to increased investment, these companies enjoyed the protections afforded by the temporary measures in CIGA and also the advantages of certain government initiatives such as the Future Fund (now closed to new applicants) (see Department for Business, Energy & Industrial Strategy: Apply for the coronavirus Future Fund (20 April 2020)).

2. Are current trends in R&I activity reflective of trends you have observed in the sector in the last five years or have there been any significant shifts?

As an overall comment, there have not been significant shifts in the last five years in R&I activity, as the factors driving (as well as protecting against) distress and insolvency in the sector are relatively stable.

Medicines

It should be noted that only a small number of drugs that begin pre-clinical testing obtain regulatory approval for use. As such, medicine companies are usually run on a lean basis, with minimal long-term commitments or on-going obligations. In addition, in some cases, a new company structure may be established for each individual product. This allows this type of entity to be wound down easily if the product for which it was set up is not progressing or has failed to achieve the desired outcome. This, in turn, also avoids debt contamination across the developer group and enables it to protect its core business should the product in development not be a success.

Furthermore, while convertible debt is available, in the life sciences sector, it is relatively uncommon for external venture or bank debt finance to be used to fund businesses in their early stages. Funding is usually provided by equity investors and is advanced in tranches with each subsequent tranche being contingent on the achievement of development or other milestones in order to fund the product up to a certain, budgeted stage of development. For further information on seed-stage funding in the sector, see Sector note, Seed-stage investments in life sciences: key legal issues and documents. It is extremely rare for a clinical study to commence without adequate funding already being in place to complete that study.

A significant hurdle for medicine companies is the considerable cash commitment required to develop a product and to fund its journey from pre-clinical testing, through phases 1 to 3 and onto the market. Moreover, it is a risky industry and the programme can fail at any time. One way in which these exposures are managed is by the medicine companies (or their investors) entering into collaborations with, or alternatively selling or licensing the product to, Big Pharma for an upfront payment, who, in turn, use their wide resources to develop and commercialise the product and return revenue to the originator company upon certain milestones being met. However, there is a risk that, after entering into such a transaction, the licensee decides that taking a product to market is not viable (either as a result of the data generated from clinical trials or a lack of market opportunity as a result of a competitive product or otherwise), and the programme either fails or is abandoned without any further development to the product, thereby eliminating any prospect of future revenue.

Medicines pricing is another important factor to consider when looking at the viability of companies in the sector. Governments across the world are closely scrutinising their healthcare spending with a view to cost cutting. In addition, medical insurance companies are also considering their reimbursement policies and flexing their buying powers. This has the potential impact that profits could be less than previously anticipated and could lead to a decision not to progress development of the product.

Medical devices

The medical devices industry consists of the manufacturing of devices to an extremely precise specification under the heavy scrutiny of regulators. The issues it faces therefore are similar to those of companies in the manufacturing sector, albeit, with the added pressure of increased regulation.

There is a wide reliance on outsourcing of some manufacturing, often overseas, to produce component parts. This brings the risk of patents and other intellectual property (IP) being shared or infringed and supply chain disruption, which can create significant creditor pressure for the company.

3. The sector is facing the triple challenge of Brexit, COVID-19 and climate change. Are these factors changing the way R&I activity is being conducted in the sector?

Brexit

Brexit has created friction in both the medicines and medical devices industries, which has, in turn, created additional stress on companies in the sector. There is now a separate regulator in the UK, which raises concerns regarding regulatory alignment (particularly if a company wishes to launch its product in both the UK and EU) and patent protection. However, to date, this concern has not come to practical fruition. In the UK, the regulator (the Medicines and Healthcare products Regulatory Agency (MHRA)) operated a grandfather arrangement which helped avoid bureaucratic delay. This meant that all existing Centrally Authorised Product (CAP) marketing authorisations (MAs) were automatically converted to UK Marketing Authorisations (UK MAs) and issued with a UK MA number on 1 January 2021. However, UK MAs are effective in Great Britain only. See MHRA: Converting Centrally Authorised Products (CAPs) to UK Marketing Authorisations (MAs), 'grandfathering' and managing lifecycle changes.

Conversely, the separation of regulation can also bring opportunity (as seen with the UK regulator's speed of approval of the COVID-19 vaccines and the success of the UK vaccine procurement programme).

Where Brexit has caused disruption for both industries is in relation to the movement of people and goods. Post-Brexit, it has been more difficult to recruit people from

the EU to the UK. Furthermore, Brexit has also created import and export difficulties which has increased costs and resulted in uncertainty and delay, which ultimately can impact on the viability of a business.

Brexit has also had an impact on the availability of funds for investment into companies in the UK due to the UK now being classed as a "Rest of the World" country. Typically, in a fund's constitution, it will set out the territories into which it can invest and the proportion of such investments. The territories are usually categorised as USA, the European Union and Rest of the World. As the UK is now no longer part of the European Union it is considered a Rest of the World country. The funding to Rest of the World countries is usually proportionally lower than to entities in the USA or in the European Union. Therefore, the amount of funding which can be provided by an individual fund may be limited for this reason. In addition, the constitution of some funds stipulates that the funds can only be invested into a European Union entity and, therefore, this would now exclude investment in any UK domiciled companies. While these constitutions can be amended and this issue will inevitably be addressed as new funds are raised, this may cause some short-term restriction on the availability of investment to UK-based companies.

COVID-19

In addition to Brexit, COVID-19 has created sharp but widely felt supply chain issues. This, in turn, has an impact on companies' funding requirements as lead times have extended.

Clinical trials are often outsourced to contract research organisations (CROs) who manage and implement the clinical trial. The lockdowns and travel restrictions arising as a result of COVID-19, difficulties in patient recruitment and concerns over the impact of trial subjects suffering from COVID-19 on clinical trial results have led to trials being shut down or significantly delayed. CROs can only manage so many trials at any one time. As a result, the delays have created a capacity issue among the various service providers meaning that it can be months before a trial slot can be scheduled. The inevitable consequence of this is that the time and funding estimates for developing products have required extension as companies continue to incur costs for a longer period while waiting for their delayed trials to commence.

Climate change

The medicines industry is not typically an energy intensive industry. As such, it does not stand out as an industry which requires radical change in order to reduce its environmental impact. However, it will have the same concerns as many other businesses.

The medical devices industry is often an intensive manufacturing industry which requires raw materials often sourced and developed overseas. This creates environmental concerns for the industry which need to be carefully managed.

Both the medicines and medical devices industries are likely to have Environmental, Social and Governance (ESG) concerns. This is being driven in large part by its investors who are increasingly scrutinising the sectors into which their funds are invested and who, themselves, have ESG compliance and reporting obligations. It is likely that businesses will now seek to set their own ESG targets, the performance of which are likely to be subject to public or, at least, investor disclosure. See Practice note, Environmental, social and governance (ESG) guidance: tools for companies and investors.

For further information on the impact of Brexit and COVID-19 on the life sciences sector, see:

- Practice note, Brexit: implications for life sciences regulations and infrastructures and Help and information note, Brexit materials: Intellectual property and life sciences.
- COVID-19: assessing the impact on life sciences businesses: checklist.
- Life Sciences Global Coronavirus Toolkit.

4. Where in the sector are you observing the most R&I activity and exposure?

Medicines

The period during the COVID-19 related lockdowns severely impacted the ability of pharmaceutical companies and CROs to undertake and complete clinical trials. This slowed down the path to regulatory approval for new medicines. The delay in completing trial phases and obtaining regulatory approval means that companies are at risk of running out of funding. The success of these businesses depends, to a large degree, on the willingness of investors to continue to fund or the availability of new investment. The reality, however, is that so long as the prospects for the products in development are promising, medicine companies will be able to secure funding, though securing new financing on attractive commercial terms and at a desirable valuation may be increasingly challenging.

Medical devices

Early-stage medical device companies tend to be smaller companies. This impacts their ability to procure ongoing investment and also to prevent or absorb cost increases. This, therefore, increases their risk of insolvency.

Both industries have significant costs to manage and, in particular, in the medicines industry, a high risk of failure of the product.

Sector insolvency regimes

5. Please outline any sector-specific legislation and industry regimes relevant to managing insolvency or debt restructuring.

There are several regimes and legislative restrictions which could affect a potential restructuring, particularly under competition law.

NSIA

The National Security and Investment Act 2021 (NSIA) came into force on 4 January 2022 and the biotech sector is within its scope. The NSIA expands the government's powers to scrutinise certain acquisitions and investments, which completed in the period following 12 November 2020, on national security grounds. There is no materiality threshold, so the legislation will potentially impact start-ups and smaller entities. The effect of the NSIA is that it could delay potential investment, M&A activity or a distressed sale if the counterparty is an overseas entity. In addition, in some cases, UK-based investors will also be subject to the regime. The NSIA requires the parties to obtain clearance to close, and failure to do so can render the transaction automatically void and expose the parties to criminal liability.

If a call-in notice under the NSIA is issued to undertake a national security assessment, either on the initiative of the Secretary of State or following a mandatory or voluntary notification under the NSIA, the prescribed review period is 30 working days, which could be followed by a further period of 30 working days, and further extended by 45 working days in exceptional circumstances. This is of particular concern to any entity which is experiencing a cash shortfall and has difficulty obtaining further investment from its existing investors.

The creation of security over the company or the assets of the company may in certain circumstances require pre-notification if it creates an interest in the company. In addition, the enforcement of security or other step-in or control rights over the company or its assets is also anticipated to be caught by the regime.

There is an insolvency carve-out in the NSIA but this exemption only applies to the appointment of administrators (and not to any other insolvency office-holders or receivers or insolvency process). Furthermore, any sale of the business or assets by an administrator would not benefit from the mandatory notification carve-out.

For further information on the NSIA, see Practice note, National Security and Investment Act 2021: Practical Law resources.

Merger control

While this is not sector-specific, it is worth noting that the merger or acquisition of medicine or medical device companies can be subject to review by the Competition and Markets Authority (CMA). This is usually a buyer risk in any distressed sale of a company. As such, it could limit the options available to a distressed entity by introducing additional transaction risk and reducing the pool of interested parties. For further discussion of the CMA's merger control procedures, see Practice note, Competition and Markets Authority: merger control procedures and Practice note, EU and UK merger control in the pharmaceutical sector.

Controls on anti-competitive conduct

Both sectors are subject to intense scrutiny from regulators in the competition law space. Furthermore, there has recently been several well-publicised actions taken by competition law regulators against companies in the sector (particularly in the medicines industry) (see, for example, CMA: CMA finds drug companies overcharged NHS (15 July 2021)). Regulators are increasingly concerned by the following:

- Pay for delay (which is an arrangement whereby one party compensates a counterparty for not entering the market with a competitor product, often arising in connection with a settlement for patent infringement).
- Anti-competitive behaviour.
- Excessive pricing.
- Illegal information exchange and market sharing arrangements.
- Misuse of patent procedures (for example, repeatedly filing and withdrawing patent applications).

It should be noted that regulation is jurisdiction-specific and, therefore, country or state specific regulations will need to be complied with in all relevant jurisdictions. The intention behind competition law regulation is to create a level playing field and to ensure that consumers are treated fairly. However, the regulations may impact upon the viability of certain products and, in turn, place entities at risk of failure.

Patent protection

The price payable for a product drops significantly when the product goes "off-patent" so there is real value in maintaining patent protection. The effect of a

product becoming off-patent may be that the product is withdrawn and, as such, the entity may have a reduced income stream.

For further information, see:

- Practice note, IP issues in health and life sciences: overview.
- Practice note, Overview of patents.

6. What impact is the Corporate Insolvency and Governance Act 2020 (CIGA) expected to have on the sector?

CIGA expanded ipso facto protection beyond essential contracts in order to protect the supply of goods and services to businesses in UK insolvency procedures. This forms part of a shifting landscape towards what looks to be a more debtor-friendly insolvency environment in the UK. CIGA provides that a counterparty cannot terminate or amend the contractual terms for the supply of goods or services solely on the basis of the recipient entering into a UK insolvency process. This effectively removes a supplier's ability to cut off supply in these circumstances and can only be avoided in some rare circumstances where the supplier can prove hardship in continuing supply. This is likely to be helpful where the insolvent company is a licensee or is reliant on the continued supply of stock.

The protection takes effect on a party entering an insolvency procedure such as administration or liquidation and disapplies any termination provisions in the contract that are prohibited by CIGA. As the protection in CIGA has automatic effect, there is no requirement to amend existing termination language in contracts in order to comply. For more information, see Practice note, Restrictions on terminating supply contracts in insolvency proceedings.

There is some argument as to whether an IP licence is a supply of goods and services as this is not defined in CIGA. However, the government has previously stated:

> "that contractual licences, such as for use of software or patents, will be covered by the 'ipso facto' provisions, acknowledging the importance of these to certain businesses and sectors."

The protection under CIGA can help an entity to continue to trade while in an insolvency process. However, in the event of a sale of the business or assets of an insolvent licensee, the provision will not assist in the assignment or sale of a licence to a third party.

The ipso facto protection, as incorporated in the Insolvency Act 1986 by CIGA, applies to contracts regardless of whether they are governed by English law. In addition, the company subject to the insolvency procedure does not necessarily need to be incorporated in England or Wales, so long as its insolvency proceeding is commenced in England or Wales. However, where either party is located in another jurisdiction or the contract is governed by foreign law, the protection afforded by CIGA may, in practice, be ineffective. In particular, its effectiveness may depend on whether the court in the relevant jurisdiction agrees to recognise both the English insolvency procedure and also the provisions of the Insolvency Act 1986. Furthermore, the process of seeking the assistance of foreign courts is likely to result in the insolvency practitioner incurring significant costs and delay which may outweigh the benefit of the protection in the legislation.

For further information on CIGA, see Practice note, Corporate Insolvency and Governance Act 2020: toolkit and tracker.

Supply chain risk

7. Where in the supply chain are you seeing the biggest areas of financial distress and insolvency risk? How is this impacting business continuity and operations in the sector?

Medicines

The transportation of medicine often requires specialist logistics and distribution service providers. This can create significant risk to pharmaceutical companies which is at its most acute when the product contains substances which may deteriorate after a limited period or when not kept in optimum conditions. In addition, Brexit has caused delays and increased costs associated with the import and export of products. In each case, these pressures increase financial risk for the companies operating in this industry.

The recent and rapid rise in energy costs may result in development cost projections being incorrect and as such may impact on cash runways (that is, the period of time the company has before cash runs out).

Medical devices

As stated above, a large majority of the manufacturing of component parts is outsourced to overseas entities. This brings risk in relation to any events in the local jurisdiction in which manufacturing is carried out and also in relation to the transportation of the items from those jurisdictions.

Another risk to supply could be caused by fluctuations in the cost of the raw materials. Similarly, the scarcity of

materials, in addition to causing prices to increase, may also result in long lead times which causes a delay in the product coming to market.

As with medicine companies, the increase in energy costs will also impact manufacturing costs for medical devices.

A lack of available, suitably skilled and experienced workers in the UK, and also overseas, will also create a disruption to the manufacture and supply of medical devices. In each case, these factors may contribute to the financial distress experienced by companies in this industry.

8. How should those in the sector seek to protect themselves against this risk to maintain supply chain continuity and resilience?

There can be a number of participants in the supply chain, such as manufacturers, packaging companies, logistics companies and distributors. Each party will need to be carefully monitored and managed.

It is essential to have sufficient terms in any licence arrangements in order to protect a licensee's position, for example, a right to acquire the IP in certain circumstances for fair market value (which may take into account the value attributed to the party's own contribution). It is also important to ensure that registrations are kept up to date.

In relation to the supply of parts or materials, a supplier may seek to introduce retention of title provisions to the contract for supply. It should be ensured that this provision is valid and enforceable. Furthermore, a supplier may wish to consider obtaining regular payments, and even upfront payments, for the supply of stock or services. Parties should also consider the breadth of the termination events under the contract (while being cognisant of the ipso facto protection in CIGA). Reliance could be sought on termination events usually associated with insolvency or insolvency procedures (rather than on the event of the insolvency procedure itself) such as closing down, or ceasing to trade, parts of the business.

The shelf life of the materials and the products needs to be kept in mind of course, so over-ordering or stock-piling goods is not always an option and would also place a burden on cash flow.

Consideration should be given to the laws of each relevant jurisdiction for the trading arrangement (considering the jurisdiction of the parties, the law governing the arrangements and the location where any actions are undertaken) considering any cross-border issues, particularly those caused by Brexit.

As in any other industry, the company directors need to review the cash runway alongside the project timetable on a regular basis. Furthermore, good credit control discipline needs to be implemented.

Companies in the sector may wish to ensure that, should it be required, contingency funding can be procured at short notice.

Acquisition opportunities

9. Please describe trends you are seeing in distressed M&A in the sector. What areas of opportunity are there for prospective buyers of distressed or insolvent companies?

There is currently a huge amount of M&A activity in the sector fuelled, in part, by the ease of access to funding and also an increased interest in IP portfolios. There is a trend of consolidation in the market, where larger entities are using an M&A process to add to their existing platform and products, thereby increasing their customer base. This activity is largely conducted on a solvent basis but there will be some distressed entities which are acquired.

Furthermore, a sale opportunity may arise as a result of the decision of the existing investors not to further fund the company. This is often as a result of the intense cash requirement of businesses in this sector to develop and commercialise their products. Alternatively, it may be that one of the investors is a fund which is nearing the end of its life and therefore can no longer retain its stake in the company.

The acquisition of a company with a developed, or partially developed, product often means that the acquirer can avoid incurring certain expenses and liabilities, including those related to clinical trials.

It is important to point out that most acquirers in this space are usually already participants in the life sciences sector and are familiar with the strict regulatory requirements associated with the industry, alongside the extensive due diligence required in relation to the IP assets.

See also Sector note, Life Sciences M&A: Q&A.

10. Are there any sector-specific risks prospective buyers should be aware of? What actions can they take to mitigate these risks?

Medicines

Of fundamental importance are the regulatory approvals in relevant jurisdictions and also any authorisations

required to market the products. These require careful review and may also necessitate a transitional arrangement between the seller and the buyer to enable the buyer to supply the product while it awaits its own regulatory approvals, which can in practice take up to 12 months. A buyer will need to carefully consider if the business is supported by the various types of qualified person required under the applicable regulations.

In addition to patent maintenance, the continuity of licence arrangements is also often core to product development and value. Therefore, it is common to see provisions in licences which deal with the scenario where the licensor becomes insolvent and may provide the licensee with a right to acquire the IP. However, this brings risks associated with the price payable for the IP, which may be subsequently challenged or prohibited, or that the anti-deprivation principle is breached by the transfer of the IP to the licensee.

Difficulties can also arise where the IP is licensed to multiple parties. Furthermore, if a licensee has not registered its interest in the licence subject matter at the UK Intellectual Property Office and in the other relevant jurisdictions where the patents have been applied for or granted, a bona fide purchaser of the subject IP may, in some instances, be deemed to have acquired the IP free of the licence. There is also a risk of the insolvency practitioner appointed over the licensor seeking to avoid honouring the terms of the licence. However, it is unlikely that a liquidator will be able to disclaim the licence unless he or she can satisfy the high burden that the licence is unduly onerous.

Data protection is also a key concern, particularly in relation to sensitive patient data which has been collated with respect to clinical trials and drug performance. This will need to be considered carefully in respect of each of the relevant jurisdictions. See Data privacy: key issues and resources for life sciences practitioners.

Medical devices

The viability and continuity of supply of materials may be essential to the development and manufacture of the medical devices and so should be closely monitored and subject to careful due diligence.

Both

IP ownership and maintenance is a matter which goes to the value of the product and, therefore, the viability of the business. It is critical to ensure that the IP is registered in each relevant jurisdiction and to verify that the scope of the registration is sufficient to enable the entity to do what it can do or what it says it will do in the future. If protection is not maintained, this could jeopardise the value of the product. Factors such as validity, duration and scope go directly to the value of the business or assets. IP infringement is also very relevant here and this should be closely monitored.

One point to note is that, in this sector, a large number of IP licences are issued by UK universities. It is important to check the termination provisions in the licences and also whether the licenses are assignable. It may be that the entity is both a licensor and separately a licensee and that the IP in the licence is issued to multiple parties. See Practice note, Overview of collaborative R&D agreements.

A buyer should satisfy itself as to the availability of experienced and knowledgeable staff and whether they are required to further develop or commercialise the product.

A further risk is in relation to the position of the relevant governments and insurance companies regarding the pricing for, and reimbursement of, the products. This may impact on the future margin of the product.

Buyers tend to already be present in the sector and so will be aware of the sector risks. They will know, for example, that they are likely to need a sophisticated infrastructure in order to integrate the purchased business and assets and to meet the requirements of the relevant regulators. There is likely to be a need for experienced employees to facilitate this.

11. How are sales of insolvent businesses generally structured in the sector?

Share sale by investors

This type of sale is typically where the investors are not willing to advance further funds to the company. However, other than the ongoing funding requirement, the company is unlikely to have significant financial liabilities.

The advantage of this type of sale is that the company is kept intact and, therefore, there should be minimal impact on the regulatory approvals. It is suitable for simple company structures.

The risk with this type of sale is in relation to change of control provisions in key contracts. A buyer should check whether a change of control of the company has an impact on any key contracts and, if so, whether this can be mitigated.

Business or asset sale via an administrator (usually a pre-pack sale)

Medicines

The value in these companies tends to be in keeping the entity whole and not in a break-up. As such, a sale of the business and assets together is more likely. However, personal authorisations and permits are not transferrable and, as such, a buyer may require a

transitional services arrangement with the seller in order to enable it to market the product while it awaits its own authorisations. MAs are transferrable but circumstances such as a change in the manufacturer would need to be reflected in the authorisation. Consideration would also need to be given to the timing of a transfer of any orphan designation, if relevant, particularly as, following Brexit, this is now managed by the MHRA. See Practice note, Orphan designation: timing, criteria and procedure.

In solvent M&A transactions, deferred consideration (often contingent on achieving agreed milestones) is common. However, this is less likely to occur in a distressed situation as it would require the administrator or liquidator to remain in office to receive such consideration. Therefore, full value is likely to be paid on completion and the risk as to the future value and efficacy of the product rests with the buyer.

In any sale the buyer will want to acquire the relevant data, including the pre-clinical testing and clinical trial data, as well as details of price reimbursement arrangements. Therefore, data privacy implications will need to be addressed.

The insolvency practitioner would also need to consider whether the transactions affect patient safety or pharmacovigilance (drug safety monitoring and reporting) systems (see, for further information, Practice note, An introduction to pharmacovigilance in the EU).

If any trials are ongoing when the company enters an insolvency process, the buyer may need to ensure that any end of trial activities are appropriately completed. For example, notifying the relevant Research Ethics Committee that approved the trial, closing down the site, accounting for all medical products and equipment and complying with the instructions of the Ethics Committee upon ending the trial. Further obligations include sending a declaration of the end of the clinical trial to the MHRA within 90 days of the global end of the trial and publishing a summary of the trial results within one year of the end of the trial, as well as submitting a final report to the Research Ethics Committee within the same timeframe for reporting the summary of results.

Medical devices

In respect of medical device businesses, an asset sale may be more likely, particularly where the manufacture of the product is outsourced. In this situation the IP portfolio, in addition to any work in progress, drawings, stock, moulds and data are likely to be the most attractive assets of the company. The IP will need to be subject to careful due diligence prior to any purchase.

The CE mark for each device is not capable of transfer to a new entity. Therefore, a buyer will need all relevant data from the seller in order to apply for the CE mark and may also require a transitional arrangement in order to market the device prior to receiving a CE mark.

For more information on asset sales via an administrator, see Practice note, Buying the business and assets of an insolvent company. For information on pre-pack sales in particular, see Practice note, Pre-packs in administration: overview.

Approaching a restructuring or insolvency process in the sector

Restructuring

12. Can you outline any sector-specific considerations and risks in a restructuring process in this sector, from the perspective of both (i) a financially distressed entity in the sector and (ii) a creditor of this type of entity?

Financially distressed entity

The largest issue for the entity will be meeting the requirements of its regulators while also being vigilant of the cash runway and availability of further funding.

There is, currently, no specific provision in UK clinical trial legislation (in particular, the Medicines for Human Use (Clinical Trials) Regulations 2004 (as amended)) in relation to solvency requirements at the start of a trial and management of the insolvency of a clinical trial sponsor during the course of a trial. However, to commence a clinical trial without certainty of funding has material ethical considerations and could call into question the exercise of the duties of the relevant directors of the company. Therefore, before each phase is started, the directors must be confident that they have obtained committed funding to pay all future costs to be incurred in that stage.

Companies in this sector are often required to engage qualified personnel who must be retained while the entity is trading. Furthermore, the company must ensure that it has sufficient funding in order to do this.

The directors of the company will also need to ensure that the necessary product liability and clinical trials insurance is in place, and that the premium has been paid.

Creditor

A creditor should ensure that it maintains a close and effective credit control procedure and that early warning signs of insolvency are identified and, if necessary, acted upon. This is particularly relevant following the introduction of ipso facto protection in CIGA. Moreover,

termination events should include events associated with insolvency and insolvency procedures (rather than on the event of the insolvency procedure itself), such as closing down, or ceasing to trade, parts of the business.

Suppliers of parts and materials could also look to incorporate retention of title provisions into their supply arrangements. Furthermore, they could insist upon only entering into supply contracts for a short and finite period which would enable termination to occur on expiry of the period (rather than upon the occurrence of a future event). For more information, see Practice note, Retention of title.

Suppliers should ensure that contracts are personal and not assignable in order to retain control should the counterparty seek to sell or transfer its business.

Insolvency

13. Are there any sector-specific considerations and risks to be aware of when advising (i) an entity in this sector that is going through a formal insolvency process and (ii) third parties dealing with such an insolvent entity in this sector?

The company

The regulation of medicines imposes a range of strict requirements which must continue to be met at all times even during an insolvency process. The legal duties of a company as a MA holder for a medicine are extensive, and an infrastructure to comply with those duties needs to be maintained.

Where there is value in the registered IP, it is essential that the filings are maintained in each relevant jurisdiction.

All IP licences should also be reviewed in order to consider whether the ipso facto protection in CIGA applies.

Consideration will also need to be given to the nature of the company's products, the conditions required for storage, the shelf life of the products and the risk of deterioration.

Third parties

Third parties should ensure that all of their rights and assets are effectively registered, particularly in relation to licences of IP rights.

Where a third party is a licensee and relies on IP owned by the insolvent entity, the third party should ensure that it has step-in rights, which will allow it to maintain any IP registrations or protections and thereby preserve the value of the IP.