Healthcare M&A 2021

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Introduction

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We are pleased to introduce the third edition of *Lexology Getting The Deal Through – Healthcare M&A*, which explores the main issues in healthcare M&A transactions. It also acts as a comparative legal guide for cross-border or multi-jurisdictional activities and a barometer for current and future sector trends in each jurisdiction.

Within the UK, the final quarter of 2020 and 2021 has seen an increase in the level of healthcare M&A activity following a drop during the covid-19 pandemic. There has been continued interest from international trade investors, particularly from the Far East; private equity, who have a heightened interest in the medical services sub sector; and infrastructure investors, who are attracted to the asset backed long-term income that is afforded from certain healthcare businesses. Within the care sector we have seen a high volume of financial restructuring and distressed M&A.

There has also been an increase in activity and corresponding regulation in the development of healthtech that enables the remote delivery of digital health products and services, as well as an increasing focus on quality, owing to the high standards imposed by regulators and a focus by the government on high levels of transparency and clarity for consumers.

We begin this edition of *Lexology Getting The Deal Through – Healthcare M&A* with an overview in each jurisdiction of key issues such as the structure of a typical healthcare-related business transaction, the timelines involved, and typical representations and warranties provided by sellers. We then go on to examine the legal due diligence required at the outset of a healthcare business combination including regulatory and compliance, employment, real estate, insurance and intellectual property, the exposure to risk if due diligence is not correctly undertaken and specific material diligence issues. The report also details some of the key completion issues – conditions, covenants and insurance and post-completion undertakings.

The regulatory framework for healthcare differs across borders and is a complex area. Each chapter provides details for each jurisdiction on the key primary laws and regulations, such as which third-party consents and regulatory notifications and filings are typically required for a healthcare business combination, and whether there are any ownership restrictions. We also outline some of the specific merger control issues to be aware of.

Then some financing and valuation issues are considered, specifically around pricing, security and financial assistance, and the typical tax issues and risks to be aware of. This is followed by public relations and government policy issues across jurisdictions that should be addressed. Material legislative or regulatory change in the sector is an inherent risk and an important factor to be considered in the context of a prospective transaction.

A new section for 2021 is dedicated to covid-19. We examine emergency legislation, relief programmes and other initiatives that each jurisdiction has put in place to address the covid-19 pandemic and we advise on best practices for clients.

Each chapter ends with some thoughts from the various contributors on current sector trends and expected developments in each jurisdiction over the coming year.

As authors of the UK chapter, we expect to see changes relating to the political climate in the UK, in particular repercussions from the covid-19 pandemic, but there is still uncertainty as to how this will develop. We hope that the pandemic will become a catalyst for a long-awaited move towards regulatory reform with the intention of greater integration and collaborative working between health and social care services. We expect an increase in outsourcing of NHS work to private providers (for example, remote diagnostics and screening) in order to help reduce current waiting lists as a result of the pandemic.

There will be increased due diligence on supply chains (which may be liable to disruption as a result of the pandemic) and business continuity measures (eg, remote working capacity and refitting of lab and office space to allow for social distancing measures).

There will be a move to bring production and other key services back onshore in the UK and an increase in local capacity in light of the demand for covid-19 vaccines. It is likely we will see a repatriation of national drug supply chains and the re-establishment of national strategic manufacturing capabilities may slow the divestment of manufacturing assets by big pharma.

Lastly, there could be a move by healthcare regulators to introduce broader regulation to better capture online services and delivery of virtual healthcare.

We hope this report serves as a useful and practical guide to getting your healthcare M&A deal through and understanding the sector landscape when working across borders. If you would like any further information on any of the points raised in the report, please do contact the CMS healthcare team or any of the other chapter authors.

United Kingdom

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TRANSACTIONAL ISSUES

Structures

1 What is the typical structure of a healthcare-related business combination in your jurisdiction?

Healthcare business combinations are largely dependent on what is being acquired or sold. Where the intention is for the whole business to transfer, a share sale is most commonly used as it allows for all assets and liabilities (such as the benefit of any contracts that the company may be party to) to transfer on completion and potentially avoids certain regulatory obstacles. Alternatively, where a business is selling only some of its undertaking (for example, to divest of its specialist care operations while retaining more generalised care operations) an asset sale will be used.

In terms of the internal structure of healthcare-related businesses, where there is a large real estate element to the operations (such as in the care home sector), the business will often utilise what is known as a 'Propco/Opco' structure, with the Propco holding title to the relevant property and the Opco taking a long-term lease from which it will operate the business.

In respect of life sciences businesses with a particular asset in development, the transaction might be structured as a joint venture between the target and a larger corporation. Typically, this would entail the incorporation of a corporate vehicle into which the development company would license or transfer the relevant asset, with the larger corporation funding the development of that asset.

In some cases, where a development company has a 'platform' technology (ie, one that can be developed for multiple applications), alternative structures have been developed to allow single applications to be spun out into independently funded special purpose vehicles while the assets continue to be developed by the development company. These structures tend to be quite bespoke.

Timeline

2 How long do healthcare business combinations usually take, and what factors tend to be most significant in determining the timing to completion?

Healthcare business combinations can take eight to 12 weeks from when lawyers are typically instructed, but could take longer depending on factors such as:

- size and complexity of the transaction;
- whether the target, buyer or seller is listed on a stock exchange or is raising external funds for the transaction; and
- whether there are any competition law, regulatory, change of control or compliance issues.

Representations and warranties

3 What are the typical representations and warranties made by a seller in healthcare business combinations? What areas would be covered in more detail compared with a more general business combination?

A seller would typically be expected to give a full range of warranties with respect to the target and its business. In addition to more general matters common to all businesses, such as capital structure, financial and commercial matters, taxation and real estate, areas that would be covered in more detail will depend on the specific business but would be likely to include:

- intellectual property ownership and freedom to operate;
- product liability;
- findings of any clinical trials in respect of life sciences businesses;
- regulatory licences and compliance, including identification of any relevant regulatory registrations and health and safety;
- data protection;
- employment and pensions; and
- litigation, inquests and investigations in respect of healthcare businesses.

Due diligence

4 Describe the legal due diligence required in healthcare business combinations. What specialists are typically involved? What searches would typically be carried out?

Legal due diligence must be tailored to match the structure of the proposed transaction and the nature of the target business. Relevant sector-specific due diligence matters may include the following.

Regulatory and compliance

A focus of legal due diligence will be to ensure that the subject entity is registered correctly with the appropriate regulatory bodies and that its current and historical performance comply with regulatory standards. This will typically involve an interrogation of online regulatory databases and an examination of registration information, inspection reports and other correspondence with the relevant regulator or regulators.

Diligence would also be conducted on the target's data protection policies to ensure they comply with the requirements under the General Data Protection Regulation (679/2016/EU) (GDPR) as healthcare operators hold their patients' sensitive personal data.

Employment matters

Healthcare can be an employee-heavy sector. Diligence would be conducted to determine:

- the nature of the employment relationships (particularly if there are any zero-hours contracts);
- compliance with the national minimum wage;

- the calculation of holiday pay;
- any employment policies in place; and
- in relation to the right to work in the UK, whether an appropriate work permit has been granted.

Real estate

In property-rich healthcare businesses, diligence would look to confirm ownership of the real estate assets.

Insurance

Diligence would look to ensure the adequacy of the insurance cover relating to medical negligence claims, employer's liability claims, abuse risk, patient safety, care quality and data security.

Intellectual property

The focus would typically be on intellectual property ownership and freedom to operate. Specialist intellectual property lawyers, commercial or licensing lawyers and patent attorneys would often be involved, with relevant searches being carried out in current and target markets.

Risk exposure

5 | If due diligence is not correctly undertaken, what specific healthcare risks might buyers inherit?

For buyers of healthcare businesses, a principal risk from inadequate due diligence is the exposure to civil and criminal enforcement action by regulatory bodies or the police where issues have not previously been highlighted and the risks mitigated. Regulatory bodies have enforcement powers that include civil action, such as imposing conditions on the service provider's registration, and suspending or cancelling the registration if they consider that appropriate actions have not been taken to address identified deficiencies or failures to meet the required standards.

In addition, a number of regulatory bodies also have criminal enforcement actions where they can prosecute for breaches of their regulations, for example, failure to meet a required standard that causes avoidable harm to a service user. Sentences for criminal offences vary, but, for example, in England, Care Quality Commission (CQC) prosecutions can result in an unlimited fine.

Any enforcement action has the potential to cause reputational damage or influence new business. If the service provider is subject to improvement action by a regulatory body, then re-registration of the same service with new buyers could be more difficult without these areas being addressed.

For life sciences businesses, liability, associated fines and reputational damage can result from the way in which a company manufactures, markets, prices and sells its products as well as how it stores and uses personal information associated with its products and their end users. For example, improper activity by a company's sales force such as offering improper incentives, or the promotion of 'off label' use, can lead to civil and criminal actions.

Specific diligence issues

6 | How do buyers typically approach specific material diligence issues in healthcare business combinations?

It is important that specialised categories of information are requested and considered when advising buyers in respect of healthcare business combinations; for example, information in respect of the number and type of safeguarding notifications, regulatory ratings and any enforcement action or unexplained deaths. Most buyers, supported by their specialist healthcare regulatory lawyers and other advisers, are aware of the risks associated with businesses of this nature and can use their experience to assess the risk profile of the target business compared to their existing business or others in the sector. The specialist advisers can advise on mitigating risks identified and actions to be taken once the transaction has completed, to help ensure that any poor practice is addressed under the new ownership. Where appropriate, indemnities supported by purchase price retentions can be sought from sellers in relation to specific identified concerns.

Conditions before completion

7 | What types of pre-closing conditions are most common in healthcare business combinations?

Third-party approvals

If the buyer is acquiring the business and assets of a healthcare facility, rather than the shares of the relevant operating company, it will need to obtain approval from the relevant healthcare regulator to operate that facility. Approvals will also be required if there are to be changes to certain regulated managers of the operating company or the specific facility, or both.

From a competition perspective, approval may need to be obtained from the Competition and Markets Authority (CMA) in respect of the proposed combination. The CMA has taken an active role in recent years in reviewing anticompetitive arrangements and potential mergers and acquisitions in the healthcare sector. Acquisitions, particularly those involving synthetic biology or critical suppliers to emergency services providers, may also require a mandatory filing (or merit a voluntary filing) to the Department for Business, Energy and Industrial Strategy (BEIS) under the National Security and Investment Act 2021 that will come into force towards the end of 2021 but apply to any transaction that has completed after 12 November 2020.

It is very common for private healthcare operators to contract with a public sector commissioning organisation such as Clinical Commissioning Groups (CCG) or local government authorities. In independent healthcare business combinations, buyers may want to obtain the approval of the applicable CCG or local authority of the target business as a condition to entering the transaction, or if the current contract between the target business and the CCG or local authority is about to expire, the buyer may insist on the target business entering into a renewed contract with the CCG or local authority as a condition to the transaction.

Life sciences businesses may also require third-party consent to the change in licensee of key in-licensed intellectual property or the transfer of intellectual property rights as well as the relevant approvals from regulatory authorities for the sites and activities they are carrying out. Where medical devices are concerned, product certificates from UK Approved Bodies or EU Notified Bodies may be required depending on the product.

Business conditions

As with many business combinations, in conducting due diligence, the buyer may have identified a key matter in respect of the target business that it would want to be rectified before completing the acquisition.

In healthcare businesses, the target business may not have rectified an issue identified by the CQC or another applicable healthcare regulator when carrying out an inspection of the healthcare facility. The buyer may request the seller to demonstrate that any major issues have been rectified.

In life sciences businesses, depending on what stage of its lifecycle the target company or key product is at, pre-closing conditions can include, for example, the successful completion of certain development or studies and completion of notified body QMS audits.

Pre-closing covenants

8 What sector-specific covenants are usually included to cover the period between agreement and completion in healthcare business combinations?

Covenants can include:

- receiving copies of any communications between the healthcare facility, applicable healthcare regulators and the Health and Safety Executive. Depending upon the type of communications, the buyer may seek additional comfort, such as consent rights in respect of any replies provided by the healthcare facility to the regulator, the ability to attend any meetings with the regulator or even comfort that nothing is done that could lead to deregistration or adversely affect the target's registration with the relevant regulator;
- receiving copies of communications with insurers, both from an entity and patient perspective, particularly if it relates to any changes to the terms of the policy, or any material claims that exceed a certain amount;
- owing to the value of the assets of a typical healthcare business, consent rights in respect of the sale or purchase or creation of encumbrances over material equipment or assets of a certain value; and
- consent rights in respect of any amendments to any key commercial agreements or procurement contracts (eg, contracts with public sector commissioning organisations).

W&I insurance

9 What specific provisions are commonly seen in warranty and indemnity insurance policies for healthcare business combinations compared with general business combinations?

There are no significant sector-specific issues, although insurers are wary of regulatory compliance warranties and may often require their exclusion or modification depending on the due diligence presented to them. To the extent relevant, insurers will look mostly at medical negligence and product liability issues and the underlying insurance coverage for those issues.

Specific documentation

10 Is there any sector-specific documentation typically used in healthcare business combinations? Does this differ depending on the structure of the transaction?

Where businesses or assets are being transferred, there are a number of change of ownership or control applications to submit. For example, the Medicines and Healthcare products Regulatory Agency requires that its application form to change the ownership of a medicinal product licence be completed and supported by documents such as a declaration of marketing status, a cancellation letter, a letter from the dosage form manufacturer and updated patient information leaflets and labels. Changing the legal manufacturer of a medical device will, for certain devices, require a successful audit of the new quality management system, a product review and the completion of the documents required by a notified body. The new legal manufacturer of a medical device will also need to draw up and sign its own declaration of conformity in respect of the medical device in question, stating that the product meets the applicable requirements of the medical devices legislation. A notice of rights form is also required to apply to the Intellectual Property Office to register a change of ownership or give notice of rights acquired in a patent or in an application for a patent.

On the healthcare side, there are unlikely to be sector-specific documents to transfer legal title to assets. However, other documentation may include applications to change the identity of the various registered entities or individuals involved in operating the relevant facility or novations of agreements such as care framework agreements, nomination agreements and service-level agreements.

Fewer documents are likely to be required on a share sale compared to an asset sale since the registrations with the relevant regulatory authority and relevant agreements are unlikely to change and assets will continue to be owned by the company being acquired.

Post-completion undertakings

11 Which post-completion undertakings are common in healthcare business combinations? Which undertakings are common?

The most common post-completion undertakings seen in healthcare business combinations are undertakings by the sellers not to compete with the business of the company it has sold (known as restrictive covenants). Given the relatively limited and skilled role of management in the sector, a buyer will often view restrictive covenants as important to protect the goodwill of the target. The form of restrictive covenants will differ in length and territory, dependent on the type of transaction and the business of the target. For example, on the sale of a care home portfolio a restrictive covenant will often prevent the seller from competing within a particular distance of the care homes in the portfolio at completion.

Post-completion undertakings are particularly relevant in healthcare business combinations where an earn-out consideration structure is used. This structure is common in life sciences transactions, given the innovative nature of this sector. Where an earn-out is used, various post-completion undertakings will be imposed on the part of the buyer to ensure that the earn-out is not jeopardised. Commonly included within this are undertakings to:

- operate the business in the ordinary course and not make material changes to the business without the seller's consent;
- not take any action with the intention of reducing or distorting the amount of the earn-out payment; and
- restrictions on capital expenditure and diverting business opportunities.

REGULATION

Laws and regulations

12 What are some of the primary laws and regulations governing or implicated in healthcare-related business combinations? Are healthcare assets subject to specific regulation that would be material in a typical transaction? Is law and regulation of healthcare national or subnational?

Healthcare regulation

The regulatory framework governing healthcare businesses differs across the four jurisdictions in the UK: England, Scotland, Wales and Northern Ireland. It is a complex area with a large number of regulations, statutory and non-statutory guidance applicable. The main legislation and appropriate regulatory body for each jurisdiction is detailed below.

The Care Quality Commission (CQC) is the independent regulator of health and adult social care in England, which includes all forms of service providers from independent hospitals to care homes. It requires service providers to register and the CQC inspects them to ensure that essential standards of quality and safety are met. The main responsibilities of the CQC are set out in the Health and Social Care Act 2008.

There are two regulatory bodies in Scotland, the Care Inspectorate (formed under the Public Services Reform (Scotland) Act 2010), which regulates services such as care homes, and Healthcare Improvement Scotland (HIS) (constituted by the National Health Service (Scotland)

Act 1978, as amended by Public Service Reform Scotland Act 2010 and the Public Bodies (Joint Working) Act 2014), which regulates independent hospitals and clinics.

In Wales, the regulatory bodies are Care Inspectorate Wales (CIW) and Healthcare Inspectorate Wales (HIW). CIW regulates services such as care homes and its function is set out in the Care Standards Act 2000 and Regulation and Inspection of Social Care (Wales) Act 2016. HIW regulates and inspects NHS services and independent healthcare providers and was established under the Health and Social Care (Community Health and Standards) Act 2003.

The Regulation and Quality Improvement Authority (RQIA) (established by the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003) regulates healthcare providers, such as independent hospitals and care homes, in Northern Ireland.

Data protection

The UK GDPR (as defined in the Data Protection, Privacy and Electronic Communications (Amendments etc) (EU Exit) Regulations 2019/419) has had a significant impact on healthcare-related business combinations. Parties are increasingly scrutinising the extent to which personal data issues may impact a transaction, particularly where the exploitation of personal data is critical for the healthcare organisation, or where personal data represents significant potential value to a buyer.

The UK GDPR has been particularly significant for healthcare organisations that typically hold and process special categories of personal data, such as health or biometric data (which is subject to stricter regulation), in addition to other categories of personal data.

Medicinal products and medical devices

Following the end of the Brexit transition period at 11pm on 31 December 2020, different legislative requirements apply in Northern Ireland compared to Great Britain (England, Scotland and Wales). Under the Northern Ireland Protocol agreed between the EU and the UK, EU law on the single market in goods (including medicines and medical devices) continues to apply in Northern Ireland and Northern Ireland is assimilated to an EU member state for these purposes.

Medicines

The Human Medicines Regulations 2012 (as amended) is the main legislation governing medicinal products across the whole of the UK, though these apply differently in Northern Ireland as compared to the rest of the UK in recognition of Northern Ireland still being subject to the EU medicines regulatory framework. In Northern Ireland, directly applicable EU law on medicines, such as Regulation 726/2004/EU also applies.

The Medicines and Medical Devices Act 2021 received royal assent in February 2021 and, amongst other things, provides a basis in primary legislation for future changes to regulation of medicines in the UK.

Medical Devices

The Medical Devices Regulations 2002 is the main legislation regulating medical devices placed on the market in Great Britain, along with the enforcement provisions set out in the Medicines and Medical Devices Act 2021.

In Northern Ireland, the regulatory framework for general medical devices is mostly contained in the EU Medical Devices Regulation 2017/745/EU which came into mandatory application in Northern Ireland on 26 May 2021 (as it did across the EU) though enforcement is still under the 2021 Act. The Medical Devices Regulations 2002 also apply certain other requirements to general medical devices in Northern Ireland as well as the greater part of the regulatory framework applicable to in vitro diagnostic medical devices. Once the EU In Vitro Diagnostic Medical Devices Regulation 2017/746/EU comes into mandatory application in Northern Ireland (as well as in the EU) on 26 May 2022 this will have direct effect in Northern Ireland at least until the democratic process foreseen under the Northern Ireland Protocol decides otherwise.

The Medicines and Medical Devices Act 2021 provides a basis in primary legislation for future changes to the medical devices regulatory regime whilst also consolidating and expanding the enforcement provisions for breaches of medical devices regulatory requirements.

Consents, notification and filings

13 What regulatory and third-party consents, notifications and filings are typically required for a healthcare business combination?

Healthcare regulators

The consents, notifications and filings differ between transactions depending on the specific entity, the healthcare service provided and the deal structure. As a general rule, if changes in legal interests, legal entities, directors and other relevant changes are occurring further up the deal structure so as not to result in changes to the entity that is actually providing the healthcare service, the requirements for consents, notifications and filings are minimised. If, however, an asset transfer of a healthcare business is contemplated, or the buyer wishes to change the details of registered managers, the registered provider, nominated individual or how the service is run, the relevant regulatory body would usually need to be notified and approvals for the changes sought. The requirements differ from regulator to regulator and continue to evolve to keep up with regulatory framework changes.

Data protection

In an asset sale, the transfer of personal data post-completion will result in a change of the data controller of that personal data. Under the UK GDPR, the new controller will need to notify the affected data subjects of that change and may need to undertake further activities where there is a transfer of marketing databases and future marketing activities are envisaged.

Competition

From a competition perspective, approval may need to be obtained from the Competition and Markets Authority (CMA) in respect of the proposed combination. The CMA has taken an active role in recent years in reviewing anticompetitive arrangements and potential mergers and acquisitions in the healthcare sector.

Following the passing of the National Security and Investment Act 2021, approval may be required from the Department for Business, Energy and Industrial Strategy for certain healthcare related transactions. The regime, which will take effect at the end of 2021, will introduce a mandatory filing regime for acquisitions within 17 defined mandatory sectors (as well as a voluntary filing procedure and call-in power for the Secretary of State for transactions and asset acquisitions in any other sector, where potential national security concerns arise). Targets engaged in activities related to the research, development and production of goods or services related to synthetic biology, and critical suppliers to the emergency services (including ambulance services) are expected to fall within the scope of the mandatory regime.

Contract counterparties

It is very common for private healthcare operators to contract with a public sector commissioning organisation such as clinical commissioning groups (CCGs) or local government authorities. In independent healthcare business combinations, buyers may want to obtain the approval of the applicable CCG or local authority of the target business or, if the current contract between the target business and the CCG or

local authority is about to expire, the buyer may insist on the target business entering into a renewed contract with the CCG or local authority.

Life sciences businesses may also require third-party consent to the change in licensee of key in-licensed intellectual property or the transfer of intellectual property rights.

Ownership restrictions

14 | Are there any restrictions on the types of entities or individuals that can wholly or partly own healthcare businesses in your jurisdiction?

Although there are no specific restrictions on organisations who own healthcare businesses, the organisation will need to satisfy the relevant regulator of their fitness and compliance with the requirements of the relevant regulations for registration to be granted. The information required will differ according to the different regulators across the four jurisdictions.

The general rule is regulators will want to be satisfied that the provider or responsible individual is 'fit and proper' to carry out the service applied for. This will require financial information to be provided, such as financial references and good character declarations (for example bankruptcy and fraud, violent or dishonesty convictions).

Directors

15 | Are there any restrictions on who can be director of healthcare businesses in your jurisdiction?

Some of the regulators across the four jurisdictions; for example, the CQC requires all directors (rather than just those with key roles) to be 'fit and proper'. This includes being of good character, not previously being responsible for any serious misconduct or mismanagement and not adjudged bankrupt or convicted of a criminal offence. Others will undertake checks on the organisation as a legal entity and responsible individuals; however, there are no specific requirements or restrictions regarding directors.

Operating outside the home jurisdiction

16 | What domestic regulatory issues might arise for a company based in your jurisdiction operating healthcare businesses in other jurisdictions?

This is very much dependent on the specific circumstances, the type of business, which jurisdictions are involved and how they operate. For example, an online GP provider with its legal entity based and registered in England, and which holds CQC registration, but provides online patient services to patients located in Scotland, is unlikely to trouble the CQC or the equivalent Scottish regulatory body. However, the CQC is likely to be concerned if, when it inspects, it appears that the service provider is demonstrating high-risk prescribing practices to patients based in another jurisdiction, which may be considered unsafe if prescribed to a patient in England. Although in this example the patient is not within England, this could still cause poor inspection ratings and requirements to be issued by the CQC in respect of safe practice. Other issues could be in respect of enforcement action (civil or criminal) in other jurisdictions, which could cause consideration as to the entity's suitability to carry on the regulated service, for example, a criminal conviction in the United States for an offence that, if convicted in England, would mean the person would be unfit to participate in the running of a healthcare provider.

Cross-border acquirers

17 | What domestic regulatory issues arise when the acquirers of healthcare businesses are based outside the jurisdiction?

The potential issues vary depending on the jurisdiction. Some jurisdictions require that the legal entity that is the service provider be based and legally registered as a company in their jurisdiction to allow them to register as a service provider with the body (for example, the CQC). Other regulatory bodies are less concerned with whether the legal entity or directors are based within their jurisdiction, but want to ensure that those legally responsible for the overall management of the service, for example, the registered manager, are accountable and based in that jurisdiction (for example, RQIA and HIS). The requirements in terms of regulation are heavily dependent on the business structure and can be complex.

An ex-UK based manufacturer of medical devices must appoint a 'UK responsible person' (or, in certain circumstances, an authorised representative, or both) established in the UK in order for its devices to be lawfully supplied in the UK. Therefore, international acquirers of the assets of a medical device business may need to have a UK entity to appoint as the UK responsible person or appoint a third party.

Competition and merger control

18 | What specific competition or merger control issues may arise in healthcare business combinations?

Healthcare business combinations may require assessment under UK merger control; however, formal notification prior to completion is currently voluntary. The Competition and Markets Authority (CMA) has responsibility for reviewing combinations of 'enterprises' under the Enterprise Act 2002, which includes public sector entities engaged in economic activities, whether by merger, acquisition, joint venture, transfers of services or long-term management contracts.

For businesses supplying public healthcare services, the CMA's substantive assessment will incorporate any likely effect on the quality of care, range of services and value of money. The CMA is now well versed in reviewing cases from the perspective of commissioners of services and end users. The latter will generally involve a local area analysis of the competitive effects.

If the CMA determines that a merger is likely to raise competition concerns, it will consider whether the prospect of adverse effects for patients and commissioners would be outweighed by the benefits of it proceeding. The views of NHS Improvement and NHS commissioning entities are sought as part of the CMA's consultation process.

In the private sector, transactions that involve private hospital operators operating, managing or otherwise providing privately funded healthcare services at an NHS private unit are similarly reviewable under UK merger control. Combinations that fall outside the scope of UK merger control may be subject to review under Part II of the Private Healthcare Market Investigation Order 2014. This involves a similar competition-based review process.

The National Security and Investment Act 2021 (NSI Act) introduces a new regulatory screening regime for investments which potentially give rise to national security concerns. The regime is expected to come into force towards the end of 2021. Acquisitions in the healthcare sector may require a mandatory (or voluntary) filing to be submitted to the Department for Business, Energy and Industrial Strategy (BEIS), particularly those involving life sciences businesses or critical suppliers to the healthcare emergency services providers. Any transaction that has completed after 12 November 2020 may also be subject to a call-in power exercisable by the Secretary of State.

State and private healthcare combinations

19 Are there any differences for healthcare business combinations if the transaction relates solely to businesses servicing private clients rather than state-funded clients?

Generally, state-funded healthcare providers in Scotland, Wales and Northern Ireland are not required to be registered with the appropriate regulatory body as an independent provider would; however, they are subject to inspection by those bodies with limitations placed on any enforcement action. In England, the CQC registers and inspects all private and NHS organisations with enforcement actions applicable to all registered providers.

In Scotland, all independent healthcare providers are required to comply with the National Health Service (Scotland) Act 1978 irrespective of whether their clients are private or state-funded.

Any private entities with a contract to provide healthcare to state-funded clients are likely to be subject to additional requirements under their contract to provide these services, to ensure that standards apply equally in state-funded and private organisations for the service user.

FINANCING AND VALUATION

Financing

20 How do buyers typically finance healthcare-related business combinations?

Buyers typically use a combination of debt and equity finance for healthcare-related business combinations.

Security

21 Describe the typical security structures in healthcare business combinations, including confirmation of any registration or notary fees in respect of the security documents.

A funder would expect to have full fixed and floating charge security over all of the assets in any target (including the shares in any target, any real property owned by that target and the interests of the buyer in the sale agreement and any tax deed). Although not strictly security, a funder may also request that its interest is noted on any warranty and indemnity insurance policy.

Security granted by any entity incorporated in England and Wales has to be registered at Companies House within 21 days of the date of its creation. The cost of filing is £15 (if made electronically) or £23 (for paper filings). Security granted over any real property located in England or Wales must be registered at Her Majesty's Land Registry. The fees payable are based upon the amount secured by the legal mortgage over the property and the value of the property that has been charged.

Financial assistance

22 Are there any financial assistance rules that arise in healthcare business combinations?

Pursuant to sections 677 to 683 of the Companies Act 2006, public companies are prohibited from giving financial assistance for the purpose of acquiring shares in its private holding company. This is relevant for share acquisitions, not where a buyer is acquiring a target company's assets.

Price and consideration

23 What pricing and consideration structures are typical in healthcare business combinations?

Both net asset value adjustments and locked-box mechanisms are seen in healthcare business combinations, with locked box being more common with private equity sellers or funds where certainty of consideration at completion is preferred.

Deferred consideration and earn-outs are also seen where value has been placed on the continuing business performance, for example where there are key contracts that the valuation relies on. It is very common for part of the consideration for life sciences businesses to be contingent on the achievement of milestone events such as product development milestones, regulatory approval milestones or, once on the market, sales milestones. This is most often the case when the target is developing a therapeutic product (as opposed to a diagnostic product or medical device) because of the longer periods taken to receive approval and reach the market and the resultant higher risks involved. Sometimes the right to receive contingent consideration is packaged as a 'contingent value right' instrument, which potentially may be tradeable either privately or on a stock exchange.

Enterprise value

24 How are healthcare-related businesses typically valued?

This will depend on the nature of the asset being acquired. Healthcare operations such as a hospital or care home business and life sciences businesses with a product on the market will typically be valued based on an EBITDA multiple. Propco values are likely to be based on the market value of the property and the forecasted rental income.

If the target has a product that is in development then often the purchase price attributable to that product will primarily be calculated on a discounted net present value basis, which will in part depend on expected pricing and reimbursement arrangements in the target markets (particularly the United States). However, it is common for more than one methodology to be applied, and buyers will often also apply example comparables before settling on a valuation.

TAX

Typical issues in combinations

25 What are some of the typical tax issues in healthcare business combinations and to what extent do these typically drive structuring considerations? Are there certain considerations that stem from the tax status of a target?

Share deal

A disposal of the shares in a target company offers the seller the opportunity of a clean break from the business, with relatively straightforward (and sometimes beneficial) tax consequences. If the seller is a company that meets the requirements of the substantial shareholding exemption (SSE) then any gains made by the seller from the sale of the shares will be exempt from corporation tax. However, if the target company had recently acquired certain assets from within the seller's group and claimed group relief on the transfer then the subsequent sale of the target company may give rise to degrouping charges (giving rise to corporation tax or stamp duty land tax (SDLT)). To the extent these charges cannot be relieved through SSE (which may be the case in respect of certain capital and intangible assets), then these charges are likely to reduce the purchase price for the target as they represent a cost for the target going forward.

Stamp duty on the acquisition of shares in a UK company will be limited to 0.5 per cent of the consideration (including, in some circumstances, contingent consideration).

Asset deal

An acquisition of the assets and business of a target company enables the buyer to choose which parts of the business it wishes to acquire and avoid taking on the target's historical and continuing tax liabilities. It should also provide the buyer with a base cost for tax purposes in the assets acquired that reflects the price paid for the assets (in contrast to the acquisition of a target company that holds assets that may have increased in value since acquisition, which would give rise to tax in respect of such gains upon any future disposal). Depending on the type of asset acquired, this may also provide the buyer with the opportunity for tax relief through amortising the asset, claiming capital allowances in respect of the asset or rolling over a historic gain into the asset.

VAT may be chargeable by the seller in respect of the assets transferred (for example, most plant and machinery). Typically, a transfer of an entire business and its assets will fall outside the scope of VAT as a transfer of a going concern. However, if it does not, this could mean that the buyer incurs VAT on the acquisition of certain assets, but is unable to recover this VAT since the buyer itself may be making VAT-exempt supplies of healthcare services. The transfer of any property will be subject to SDLT at 2–5 per cent of the consideration for that property, the cost of which may be significant.

Tax risks for healthcare businesses

26 What are the typical tax risks that are associated with healthcare businesses? What measures are normally taken to mitigate those typical tax risks in healthcare business combinations?

The supply of most healthcare-related services is exempt for VAT purposes. This means that the business is unable to recover VAT incurred by it on its acquisitions of goods and services for the purpose of making such supplies, thereby increasing its costs by 20 per cent. Certain healthcare supplies are not exempt from VAT, for example, sales of drugs. Where a business is making both exempt and taxable supplies then it will need to apply strict policies regarding its VAT recovery, and this will always be a key risk area to thoroughly review as part of due diligence.

Healthcare businesses often engage significant numbers of locums and contractors either directly or through personal service companies. Scrutiny should be given to payroll compliance to ensure that persons (including locums and contractors) who are in effect acting as employees are remunerated and taxed as such, with appropriate PAYE deductions and employer national insurance contributions made.

PUBLIC RELATIONS AND GOVERNMENT POLICY

Public relations

27 How do the parties address the wider public relations issues in healthcare business combinations?

Where there is an element of public finances that underpin a target business the implications will need to be considered in the context of any transaction. Similarly, many businesses will involve the direct provision of services to patients and vulnerable persons and accordingly the wider public aspect will be a factor. In many cases, particularly in the context of trade deals (where both parties are already operators in the sector), the buyer and the seller will take huge comfort from the fact that the transfer of the underlying business or asset will result in no material change to the continuation of the underlying business (and, in fact, could result in an enhancement to the services provided) and, accordingly, while there will be an element of financial return occasioned by the transaction, there will be material benefit that arises for patients and the wider community.

The parties will also have regard to the fact that many elements of healthcare in the UK are, and have for some time, been operated by the private sector and this provides benefits for the public health services and ensures the provision of services to the wider community.

It should further be recognised that in many healthcare transactions (though not in life science ones) a healthcare regulator will have provided its consent or approval to the transaction, thereby recognising that while there will be financial returns arising, these regulators are comfortable with the identity of the buyer of the relevant target business or assets from a care perspective.

Policy

28 How do parties address the wider political issues in healthcare business combinations?

Material legislative or regulatory change in the sector is an inherent risk – and an important factor to be considered in the context of a prospective transaction. In sectors where transactional activity is attractive (child care and dentistry, for example), it will generally be the case that a prospective buyer will invariably use the services of a political due diligence specialist to ensure that the management team and the board of the buyer is advised of the current and prospective political climate that the target business will encounter over the proposed ownership period. Similarly, independent consultants may be engaged on a transactional basis to advise the buyer during the currency of the transaction.

Occasionally, the political or regulatory climate will result in a slowdown in transactional activity in a particular sector – an example being the slowdown in the M&A activity in the hospital sector as the Competition and Markets Authority undertook a market study of the practices of private hospitals over a sustained period ending in 2016.

Government policies that lean towards more public provision of health services as opposed to private provision (with public funding) are a constant consideration, especially for those that might not have an existing sector footprint. However, the continued activity across the wider space suggests that this threat is not the cause for concern that it could otherwise be expected to be.

UPDATE AND TRENDS

Recent developments

29 What are the current trends, and what developments are expected in healthcare business combinations in your jurisdiction in the coming year?

Current trends include:

- an increase in the level of healthcare M&A activity follow a drop during the covid-19 pandemic;
- financial restructuring and distressed M&A in the elderly care home sector;
- continued interest from overseas trade investors (including from the Far East) and private equity, particularly since the United States is beginning to be seen as overvalued in the life sciences space;
- continued interest in the sector from infrastructure investors who are attracted to the asset backed long-term income that is afforded from certain healthcare businesses;
- a heightened interest in the medical services subsector from private equity investors;
- increased activity and corresponding regulation in the development of healthcare technologies that enable the remote delivery of products and services (eg, apps); and
- an increasing focus on quality owing to the high standards imposed by regulators and a focus by the government on high levels of transparency and clarity for consumers.

Expected developments include:

- changes relating to the political climate (in particular repercussions from the covid-19 pandemic) will be key and there is still uncertainty as to how this will develop;
- increased due diligence on supply chains (which may be liable to disruption as a result of the covid-19 pandemic) and business continuity measures (eg, remote working capacity and refitting of lab and office space to allow for social distancing measures);
- a move to bring production and other key services back onshore and an increase in local capacity in light of the demand for covid-19 vaccines;
- repatriation of national drug supply chains and the re-establishment of national strategic manufacturing capabilities may slow the divestment of manufacturing assets by big pharma;
- a move by healthcare regulators to introduce broader regulation to better capture online services and delivery of virtual healthcare;
- a move towards regulatory reform with the intention of greater integration and collaborative working between health and social care services; and
- an increase in outsourcing of NHS work to private providers (for example, remote diagnostics and screening) in order to help reduce current waiting lists as a result of the covid-19 pandemic.

Coronavirus

30 What emergency legislation, relief programmes and other initiatives specific to your practice area has your state implemented to address the pandemic? Have any existing government programmes, laws or regulations been amended to address these concerns? What best practices are advisable for clients?

On 27 March 2020, the Competition Act 1998 (Health Services for Patients in England) (Coronavirus) (Public Policy Exclusion) Order 2020 (SI 2020/368) came into force. The Order allows independent healthcare operators to enter into agreements with the NHS or one another, or both, which might otherwise breach competition law, where the purpose of such agreements is to support the NHS in its response to coronavirus. The Order lists 'qualifying activities', which include activities such as information sharing in relation to capacity, co-ordination as regards the deployment of staff and the sharing of facilities to provide healthcare services. The exclusions apply for the duration of the 'healthcare disruption period', which commenced on 1 March 2020 and is ongoing until the Order is revoked. Any such agreements must be notified to the Secretary of State within 14 days of being entered into.

The Coronavirus Act 2020 was brought into force on 25 March 2020 on an emergency basis. One of the measures provided for by the Act was the emergency and temporary regulatory registration of some healthcare professionals, such as recently retired doctors, in order to meet the high demand for healthcare. Another was the temporary modification of mental health and capacity legislation to, for example, increase periods of lawful detainment and expand the range of individuals who could make an application for compulsory hospital admission. Some of the provisions of the Act have now been repealed whereas others either remain in force or have not yet been brought into force. Healthcare regulators have taken advantage of legislative changes to streamline regulatory processes previously constrained by legislation, such as holding tribunal hearings remotely instead of in person, and many intend to maintain such changes going forward. Service providers should carefully check the current measures to ensure that target companies remain compliant.

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ISBN 978-1-83862-670-9