United Kingdom

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Overview

1 In general terms, how is healthcare, including access to medicines and medical devices, funded in your jurisdiction? Outline the roles of the public and private sectors.

The majority of healthcare in the UK is provided by the publicly funded National Health Service (NHS). In 2013, public sector spending accounted for 83.3 per cent of the total healthcare expenditure in the UK of approximately £125.5 billion. The NHS budget for the 2015-2016 financial year is £115.4 billion.

With some exceptions (such as prescriptions in some parts of the UK), the NHS is free at the point of use. The vast majority of funding for the NHS (98.8 per cent in 2013) is generated through general taxation and national insurance contributions from employees and employers. The rest of the NHS is funded through patient charges.

Private medical care is also available, the majority of which is funded through private medical insurance policies. Some private medical treatment is purchased by the NHS, and a small minority of individuals self-pay for private medical treatment.

2 In general terms, how is healthcare delivered in your jurisdiction? Outline the roles of the public and private sectors.

The Secretary of State for Health has overall financial control and oversight of all NHS delivery and performance in England. Responsibility for healthcare in Wales, Scotland and Northern Ireland is devolved to the relevant minister in each country.

In the public sector, healthcare is delivered either by general practitioners (GPs), NHS walk-in centres and pharmacists (known as primary care) or by hospitals (known as secondary care). As discussed below, the structure of primary and secondary care providers is very different, though they all provide care that is free at the point of use.

In contrast, private healthcare is delivered by either business enterprises or non-profit-making trusts. Many private healthcare groups, such as BUPA, provide private medical insurance and operate private hospitals for those insured by them, or those who self-pay for private treatment.

3 Identify the key legislation governing the delivery of healthcare and establishing the regulatory framework.

In April 2013, the NHS underwent a significant reorganisation through the introduction of the Health and Social Care Act 2012 (the Act). The Act created a commissioning board known as NHS England, which is now responsible for commissioning healthcare services in England. While NHS England commissions some services directly, at a national level, most commissioning is now done by consortia of GPs, known as clinical commissioning groups (CCGs). CCGs hold approximately 60 per cent of the NHS budget.

The Act abolished the former commissioning bodies, primary care trusts. It also established Public Health England, a body charged with protecting and improving the nation's health and wellbeing, and Healthwatch UK, the 'consumer champion' for health and social care.

The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (HSCA (RA) 2014) introduced new 'fundamental standards', applicable to the care provided by registered providers, as well as a statutory 'duty of candour'; and a 'fit and proper persons' requirement for directors and equivalent employees.

4 Which agencies are principally responsible for the enforcement of laws and rules applicable to the delivery of healthcare?

The Care Quality Commission (CQC) is the independent regulator of health and social care services in England. It regulates hospitals (including private hospitals), care homes, dental and GP surgeries, and all other care services in England. It is funded by a combination of a grant from the Department of Health and registration fees. While it has the power to levy fines against service providers, its funding is not dependent on the amount of fines imposed or paid.

Medicines and medical devices are regulated by the Medicines and Healthcare Products Regulatory Agency (MHRA). The MHRA operates as a government trading fund, which means that the majority of its income is generated by fees it charges. However, this income does not include fines.

The independent sector regulator for health services in England is an entity called Monitor. Like the CQC, it is also primarily funded by the Department of Health and is not funded by the fines that it has the power to impose.

5 What is the scope of their enforcement and regulatory responsibilities?

The CQC registers health and social care providers and managers, and sets essential standards for health and social care service providers in England, pursuant to the HSCA (RA) 2014 and the Care Quality Commission (Registration) Regulations 2009. It also monitors providers' performance against these standards.

Prior to 2013, Monitor's main role was to authorise, monitor and regulate NHS foundation trusts (which provided secondary care, and accounted for over 60 per cent of NHS trusts). Monitor's role was expanded under the Act such that its responsibilities now include ensuring that procurement, choice and competition operate in the best interests of patients.

Regarding enforcement and regulations, Monitor is now responsible for, inter alia, preventing anti-competitive behaviour, and regulating licensed providers to prevent them from failing financially.

6 Which agencies are principally responsible for the regulation of pharmaceutical products and medical devices?

The regulation of the safety, quality and efficacy of medicines, and medical devices, is undertaken by the MHRA. In particular, it is responsible for ensuring that medicines and medical devices supplied to the public (either through the NHS or privately) meet the necessary standards and regulations.

The MHRA charges fees to pharmaceutical companies for a variety of the tasks which it carries out, including applications for new marketing authorisations, or variations to existing authorisations (which accounted for 44 per cent of its fee income in 2014-2015); service fees for the monitoring activities undertaken by the MHRA; and inspections. It also receives grants from the Department of Health.

7 What is the scope of their enforcement and regulatory responsibilities?

On the medicines side, the MHRA primarily seeks to enforce the Human Medicines Regulations 2012. These regulations, the product of an MHRA review, consolidated and amended much of the Medicines Act 1968 and around 200 further statutory instruments.

The new regulations set out a comprehensive framework for the authorisation of medicinal products for human use; the manufacture, import, distribution, sale and supply of those products; labelling and advertising; and pharmacovigilance.

On the medical devices side, the MHRA derives its enforcement powers mainly through the Medical Devices Regulations 2002 (which implements the Medical Devices Directive (93/42/EEC) into UK law), the Consumer Protection Act 1987 (CPA 1987) and General Product Safety Regulations 2005 (GPSR 2005).

These encompass, inter alia, the investigation of allegations of non-compliance; monitoring the activities of those bodies designated by the MHRA to assess the compliance of manufacturers; and investigating medical devices based on vigilance reports or intelligence.

8 Which other agencies have jurisdiction over healthcare, pharmaceutical and medical device cases?

Healthcare professionals and organisations may be investigated by the police and prosecuted by the Crown Prosecution Service (CPS) for offences including gross negligence manslaughter, corporate manslaughter and, as of 13 April 2015, ill treatment or wilful neglect. The Serious Fraud Office (SFO) has jurisdiction to investigate the most serious fraud and corruption cases. For example, the SFO prosecuted the pharmaceutical company Goldshield and others (including individuals) for conspiracy to defraud the Department of Health arising out of a cartel that is alleged to have operated between 1998 and 2000. In 2008, the House of Lords concluded that price-fixing did not amount to a common law offence and the proceedings were dismissed shortly after (though civil proceedings by the Department of Health continued and were later settled).

In relation to competition matters, while one of Monitor's responsibilities includes ensuring that anti-competitive behaviour by commissioners or providers of healthcare services does not harm patients, the Competition and Markets Authority (CMA) as the national competition authority, or the European Commission (EC), has the power to investigate potential infringements of competition law. Both the CMA and the EC have the power to impose substantial fines for breaches of competition law.

9 Can multiple government agencies simultaneously conduct an investigation of the same subject? Does a completed investigation bar another agency from investigating the same facts and circumstances?

In theory, there is no restriction on the number of agencies that can investigate any particular subject, and each of them is free to pursue investigations as they see fit.

However, in practice, mindful of the need to avoid duplicating expenditure, many agencies have agreed procedures in place to ensure that the same conduct is not investigated by multiple agencies. For example, in February 2015, the CQC and Monitor signed a memorandum of understanding (MoU) setting out the framework for joint or parallel investigations between the two regulators.

This cooperation is formalised in the form of 'operational annexes' to the MoU, which set out the detailed working arrangements and processes. This requires both organisations to work together to identify what action is needed, and provides for the possibility of a lead regulator. Further, inspections and reviews may be carried out jointly or in parallel.

In section 3(d) of Annex B of the MoU, it is stated that any use of powers by Monitor does not preclude the CQC from taking enforcement action in relation to breaches of registration requirements or any other regulatory activity if it is appropriate to do so.

Equally, any CQC enforcement activity does not preclude Monitor from exercising its enforcement powers in relation to breaches of licence.

The SFO and the CMA have also entered into an MoU that will regulate which agency investigates allegations of criminal cartels, including in the healthcare sector. Broadly speaking, the CMA will lead an investigation into alleged cartels, but will refer any matters falling within the SFO's remit to the SFO, which can then decide whether to accept the case or not (in which case the CMA will continue with the investigation).

Regulation of pharmaceutical products and medical devices

10 What powers do the authorities have to monitor compliance with the rules on drugs and devices?

The MHRA carries out a range of inspections. These include regular inspections of manufacturing sites, and samples of medicines, to ensure compliance with the relevant rules, but also inspections where there has been an allegation of non-compliance or where a potential problem has been identified.

MHRA enforcement officers and inspectors have the power to conduct site inspections and to require the production of records and take copies, seize or detain suspect records or goods, for example under the CPA 1987.

Beyond this, the MHRA facilitates a reporting scheme, and undertakes market surveillance, and a sampling scheme of high-risk products which are most likely to be counterfeited in the UK.

Further monitoring powers include internet vigilance: the configuration of web crawling software to monitor the internet for websites that engage in illegal advertising, supply and distribution of medicines and medical devices.

11 How long do investigations typically take from initiation to completion? How are investigations started?

According to the British Society of Interventional Radiology, on average, 50 per cent of 'specialist' investigations (ie, those undertaken directly by the MHRA) are concluded within 21 weeks. Meanwhile, 50 per cent of 'monitored' investigations (ie investigations conducted by the manufacturer, on the MHRA's behalf) are concluded within 10 weeks.

Investigations may be initiated by a complaint, which may be submitted by a number of sources including members of the public (through the 'yellow card' scheme where members of the public can report adverse side-effects directly), healthcare professionals and competitor companies, or through inspection or proactive monitoring conducted by the MHRA.

The MHRA case referral centre receives all complaints of alleged breaches of medicines legislation. It will assess the referral, in terms of risk, and consider whether it falls within the MHRA's responsibilities.

If it does, the referral centre will allocate the case to a member of the enforcement group for investigation. Cases falling outside the responsibilities of the MHRA will be referred to the relevant agency.

12 What rights or access does the subject of an investigation have to the government investigation files and materials?

This depends on the type of investigation. Different rules will apply to a criminal prosecution than to an investigation by the MHRA, for example.

Where an investigation by the MHRA is instigated by a third party, the MHRA will generally keep the identity of the third party confidential if asked to do so. If the investigation relates to the safety of a medicine or medical device, then certain information will naturally be shared with the subject of the investigation. Indeed, in many cases the subject of the investigation will carry out analysis of products, etc, themselves under the supervision of the MHRA.

When a criminal investigation is underway, there is usually very little disclosure to the subject of the investigation until formal charges are made, at which point the criminal rules of evidence apply and a significant amount of disclosure is required.

The MHRA and other regulators are public bodies and therefore fall within the scope of the Freedom of Information Act 2000 (FOIA). The FOIA entitles any person requesting information from a public authority to be informed whether that information is held (the duty to 'confirm or deny'), and to have the information communicated to them, subject to certain exceptions.

The European Medicines Agency and the Heads of Medicines Agency have prepared guidance to national authorities (such as the MHRA) in determining what information should be disclosed pursuant to such requests.

13 If pharmaceutical products or medical devices are made in a foreign country, may the authorities conduct investigations of the manufacturing processes in that other country?

It is likely that if there are concerns about products manufactured in a foreign jurisdiction, the authorities in the UK would refer the matter to the appropriate authority in that foreign country, rather than undertake investigations abroad themselves.

14 Through what proceedings do agencies enforce the rules?

The MHRA has enforcement powers conferred on it, in relation to both medicines and medical devices, through the Human Medicines Regulations 2012, the CPA 1987, the Medical Devices Regulations 2002 and the GPSR 2005.

These enable the MHRA to investigate possible breaches of the relevant regulations itself and without the need to take the matter to court. For the most serious breaches, the MHRA is able prosecute defendants before the criminal courts, but this is usually only done as a last resort, where a serious offence has been committed or all other measures to secure compliance have failed.

15 What sanctions and other measures can the authorities impose or seek in enforcement actions against drug and device manufacturers and their distributors?

The principal sanction available to the MHRA is the power to issue notices, with which the recipient must comply. These notices can require the subject to provide further information, suspend or even prohibit the sale of particular products and require products to be recalled from the market. The MHRA can also obtain injunctions from the civil courts where necessary, for example in order to prevent the advertisement and supply of medicines that have not been properly authorised

It is possible for fines to be imposed following a successful prosecution by the MHRA.

16 Can the authorities pursue actions against employees as well as the company itself?

Yes. The MHRA and the CPS may pursue actions against employees (and ex-employees) of the company, including its directors. Successfully prosecuting corporates is difficult in the United Kingdom (unlike, for example, the United States) because of the requirement to show that there was a 'directing mind' of the corporate which authorised the relevant conduct. The focus of prosecutions has therefore tended to be against individuals.

For example, in 2013 the MHRA successfully prosecuted an ex-employee of a clinical research organisation, Aptuit, for illegally changing pre-clinical trial data to obtain a positive result, with a view to securing approval for clinical trials.

Notices served by the MHRA tend to be addressed to the company in question rather than individuals.

17 What defences and appeals are available to drug and device company defendants in an enforcement action?

The defences available depend on the legislation the MHRA is seeking to enforce in any particular enforcement action.

For example, in proceedings under the CPA 1987, one defence is that a defect is attributable to EU law, or that the defect did not exist in the product at the relevant time.

The appeal route depends on the decision taken by the MHRA. In general, appeals against MHRA enforcement decisions are made directly to the courts. In certain circumstances (for example an appeal against a notice to warn under the CPA 1987) appeals are made by way of arbitration under the supervision of the Chartered Institute of Arbitrators.

18 What strategies should companies adopt to minimise their exposure to enforcement actions and reduce their liability once an enforcement action is under way?

An obvious way of minimising the risk of enforcement action by the MHRA is to ensure that robust systems are in place to ensure compliance with the relevant regulations, as well as good manufacturing and distribution practice.

If a problem does arise and some form of enforcement action is contemplated, then the priority of the company must be to cooperate fully with the MHRA or other investigating authority and reduce the risk of a prosecution or other severe sanction.

19 What have the authorities focused on in their recent drugs and devices enforcement activity and what sanctions have been imposed?

The MHRA's key objectives for this year include progressing work on EU negotiations in the field of clinical trials, falsified medicines and devices, and improving incident and safety reporting systems, chiefly the yellow card scheme.

In the last year, the MHRA has taken the following action:

- Conducted a joint investigation with the Metropolitan Police, which resulted in a sentence of 27 months' imprisonment against an individual, for her involvement in the supply of abortion pills, with the intent to unlawfully procure miscarriages.
- Taken action against two companies, for selling faulty pre-filled syringes, which resulted in the death of a diabetic patient and amounted to a violation of the Medicines Act 1968. Fines of £500,000 and £50,000 were imposed.
- Upheld a complaint made by Johnson & Johnson, in relation to a TV advertisement produced for a traditional herbal medicine, licensed on the incorrect assertion that the efficacy had been demonstrated.

20 Are there self-governing bodies for the companies that sell pharmaceutical products and medical devices? How do those organisations police members' conduct?

The Association of the British Pharmaceutical Industry (ABPI) is the trade association of companies in the UK that produce prescription medicines and has produced a code of practice for its members (the ABPI Code). The ABPI Code covers issues such as advertising of medicines and the activities of sales representatives. The Code is administered by the Prescription Medicines Code of Practice Authority (PMCPA).

The PMCPA has entered into a memorandum of understanding with the MHRA concerning investigations of matters falling within the scope of the ABPI Code, which is in essence that the PMCPA is the first means of dealing with complaints, though the MHRA can intervene where there is a clear case for intervention. Similarly, the PMCPA has agreed a memorandum of understanding with the SFO that provides that any alleged breach of the ABPI Code which is also a potential breach of the Bribery Act 2010 will in the first instance be dealt with by the PMCPA.

When a complaint is made to the PMCPA, a code of practice panel determines whether a breach of the ABPI Code has taken place and, if so, the appropriate penalty. Decisions of the panel can be appealed to the Code of Practice Appeal Board. Where a breach is identified, the company is required to give an undertaking that the practice in question has ceased. Ultimately, the PMCPA can suspend or expel a company from the ABPI.

Relationships between healthcare professionals and suppliers

21 What are the rules prohibiting or controlling the financial relationships between healthcare professionals and suppliers of products and services?

Regulation 300 of the Human Medicines Regulations 2012 regulates inducements and hospitality between persons qualified to prescribe and supply medicines (PQPS), and persons promoting medicinal products.

It prohibits gifts to PQPS unless they are inexpensive, being less than £6 excluding VAT, and have a clear business use, relevant to the practice of medicine and pharmacy.

Section 6.14 of the MHRA Blue Guide, on the advertising and promotion of medicines in the UK, details the two stages involved in Regulation 300.

First, there are the broader limits that catch promotion of medicines, encompassing price promotions, loyalty schemes and bonus schemes. Secondly, within that broad remit, it prohibits the supply, offer or promise of pecuniary advantage to PQPS.

The Bribery Act 2010 in the UK and the Foreign Corrupt Practices Act 1977 in the USA (which has long-arm jurisdiction) are also relevant to the financial relationships between PQPS and suppliers.

22 How are the rules enforced?

Regulation 303 makes it a criminal offence to breach Regulation 300(4) by either soliciting or accepting inducements or hospitality falling outside the exceptions under Regulation 300(1) and 300(2). This essentially covers both sides of such a transaction.

Any such breach would be a summary-only offence, prosecuted in the magistrates' court, with a maximum fine of £5,000. A prosecution can be brought by the MHRA.

23 What are the reporting requirements on such financial relationships? Is the reported information publicly available?

The European Federation of Pharmaceutical Industries and Associations agreed a Disclosure Code in June 2013. From 2016, it will become compulsory for every member company to disclose certain payments made by pharmaceutical companies to individual health care providers (HCPs) and healthcare organisations (HCOs), made in 2015, and thereafter into the future.

This mirrors the Physician Payments Sunshine Act in the United States, which requires disclosure of payments or other transfers of value made to doctors or teaching hospitals.

Under the code, pharmaceutical companies need to disclose details paid to HCPs or HCOs, or to employees on their behalf, for services such as chairing and speaking at meetings.

The information is published on a public platform (either the company's website, or a central website). Disclosures should be publicly available in the country where the HCP or HCO receiving a transfer of value or payment from industry has their practice.

Regulation of healthcare delivery

24 What powers do the authorities have to monitor compliance with the rules on delivery of healthcare?

Monitor use a risk assessment framework to monitor licence providers, and to ensure that, for example, NHS foundation trusts meet the conditions of their licence, are financially sustainable to ensure continuity of services, and that they meet governance requirements.

The CQC uses a process of continuous monitoring, examining over 150 indicators (intelligent monitoring). Factors include waiting times, mortality rates and feedback from service users. Action taken by the CQC depends on the variation identified, and includes carrying out an inspection or contacting the service to find out more information.

Both Monitor and the CQC have the power to require those they regulate to provide information or documents to them.

25 How long do investigations of healthcare providers typically take from initiation to completion? How are investigations started?

Neither Monitor nor CQC publish average investigation time frames, and the time taken can vary enormously depending on the scope of the investigation.

When Monitor becomes aware of a potential breach, it will first consider its 'prioritisation framework'. Regard is given to the importance of a breach and the benefits and costs of commencing an investigation.

Monitor will then decide whether to formally investigate a matter or to make a provisional finding that there has been a breach or infringement.

It will notify the relevant entities, setting out what it intends to investigate, the key contacts at Monitor and the expected timetable. Appropriate information is published on Monitor's website.

The CQC's intelligent monitoring helps it to decide when, where and what service user to inspect. This is the beginning of its formal inspection process. Inspectors examine health providers against a standard set of 'key lines of enquiry' to assess whether they are meeting the required standards.

The CQC also rates services into categories of 'outstanding', 'good', 'requires improvement' or 'inadequate'. The rating will determine the enforcement action taken by the CQC.

26 What rights or access does the subject of an investigation have to the government investigation files and materials?

There is no general right to disclosure of the regulator's files and materials during the course of an investigation. However, when enforcement action is taken by either Monitor or the CQC then certain information must be communicated to the subject of the enforcement action. For example, when Monitor issues a notice setting out the enforcement action it intends to take, the notice must include a statement of the evidence and the reasoning behind the proposed enforcement action.

Where there is a criminal prosecution then the ordinary rules of disclosure in criminal cases will apply.

27 Through what proceedings do agencies enforce the rules?

Monitor has the power to conduct its own proceedings, which are civil in nature. When matters are referred to Monitor, the first step is to ascertain whether to take any action and, if so, whether it should be formal or informal action. Cases are prioritised to ensure that Monitor uses formal enforcement action (and the resources which are required to pursue such an action) in appropriate cases

If Monitor intends to use its formal enforcement powers to impose a discretionary requirement, it first issues the provider with a Notice of Intent, which sets out the proposed course of action and basis for it The provider is entitled to make representations to Monitor, following which Monitor decides whether to impose the discretionary requirement in its original form, in a modified form or not at all. A Final Notice is then issued, which the provider can appeal to the First-Tier Tribunal, a specialist court.

It also has concurrent powers with the CMA to take action in respect of anti-competitive practices, and abuses of a dominant position in the market under section 72 of the Competition Act 1998 and articles 101 and 102 Treaty on the Functioning of the European Union.

The CQC has its own enforcement powers. These encompass those who carry out regulated activity without the appropriate registration with the CQC, and also those registered persons who breach conditions of their registration or breach the relevant legislation (eg, Care Quality Commission (Registration) Regulations 2009, HSCA 2008, HSCA (RA) 2014).

The CQC can pursue both civil and criminal actions. The former are carried out through its own proceedings, while the latter are prosecuted by the CQC in the criminal courts.

28 What sanctions and other measures can the authorities impose or seek in enforcement actions against healthcare providers?

When initiating a formal investigation, Monitor can use its powers under section 104 HSCA 2012 (the information provision), to require documents and information to be provided to it.

Monitor may also impose 'discretionary requirements' in relation to licensing breaches, which may result in a monetary penalty, a 'compliance requirement' to prevent further breaches, or a 'restoration requirement' to remedy the consequences of the breach (section 105 HSCA 2012).

Monitor may further impose enforcement undertaking requirements (eg, to secure that the breach does not occur again) (section 106 HSCA 2012), or impose licence conditions removing, suspending or disqualifying directors (section 111 HSCA 2012).

The CQC has the power to issue requirement notices, which identify steps to be taken to ensure compliance with the regulations. It can issue warning notices to registered persons, which outline failures and impose a deadline for compliance. The CQC can also impose conditions on, or suspend, a registration and in extreme circumstances can cancel a registration outright, urgently if required.

The CQC also has the power to prosecute criminal offences, which are heard by the criminal courts.

The CMA has extensive powers to investigate healthcare providers and to impose substantial fines in the event of a finding that they have engaged in anti-competitive conduct.

29 What defences and appeals are available to healthcare providers in an enforcement action?

Subjects of enforcement action by both the CQC and Monitor have the right to make representations during the enforcement process.

Appeals against the imposition of a discretionary requirement, a penalty, an enforcement undertaking or a licence revocation by Monitor are made to the First-Tier Tribunal.

Similarly, appeals against civil enforcement action (save for warning notices and penalty notices) taken by the CQC are also to the First-Tier Tribunal. Appeals against a criminal conviction obtained after prosecution by the CQC are to the appropriate criminal court (the Crown Court or the Court of Appeal).

Appeals against findings of the CMA are to the Competition Appeal Tribunal (CAT).

30 What strategies should healthcare providers adopt to minimise their exposure to enforcement actions and reduce their liability once an enforcement action is under way?

Again, healthcare providers can reduce their exposure to enforcement actions by ensuring that their systems are suitable to prevent any breach of the relevant regulations and that if a breach does occur it is swiftly identified and corrected.

For example, providers should consider the five key questions the CQC pose. are services safe, effective, caring, responsive to people's needs and well-led?

If enforcement action is contemplated, then full and transparent engagement with the regulator is likely to minimise the prospect of an adverse outcome for the healthcare provider. Regulators have limited resources and are likely to focus resource-intensive activity (such as formal enforcement action) on those providers who do not engage properly with them

31 What have the authorities focused on in their recent enforcement activity and what sanctions have been imposed on healthcare providers?

In its 2015-2016 business plan, the CQC has stated its intention to implement and improve a new approach to regulation, following guidance issued in Sir Robert Francis QC's Report into the Mid Staffordshire NHS Foundation Trust. This involves a renewed focus on taking action against people and services that do not meet fundamental standards.

This year, the authorities have taken the following action:

- In February 2015, the CQC issued a warning to Le Grand Nursing Home, to improve standards of care.
- In April 2015, the regulator fined St Helens Care Home £4,500 for failures to meet national standards
- In June 2015, Monitor found Lancashire Teaching Hospital NHS Foundation Trust in breach of its licence, due to a lack of robust financial plans. It imposed a condition on the Trust's licence to ensure its concerns were addressed but did not impose a financial penalty.

32 Are there self-governing bodies for healthcare providers? How do those organisations police members' conduct?

The medical royal colleges maintain an important role in setting and monitoring professional standards for their members. These include the Royal Colleges of General Practitioners, Nursing, Surgeons and Physicians.

In the private sector there is the Association of Independent Healthcare Organisations, the trade association for independent healthcare organisations that operates the voluntary Independent Sector Complaints Adjudication Service.

33 What remedies for poor performance does the government typically include in its contracts with healthcare providers?

The NHS 'standard contract' is mandated by NHS for use by commissioners for all contracts for healthcare other than primary care.

This standard contract enables the relevant commissioning body to impose financial sanctions for breaches of national quality standards. Penalties in excess of £1,000 must be reported. Unless indicated otherwise, the proceeds are all reinvested in patient services.

Sanctions relate to issues such as waiting times, cancelled operations and mixed sex accommodation breaches. Penalties are based on whether an operational standard is met.

Commissioners of primary care services also generally include provisions to recover costs in the event of poor performance. For example, in 2014-2015 Bedfordshire Clinical Commissioning Group reported penalties applied of £41,894.68 in relation to failures to meet a 90 per cent target of patients starting treatment within 18 weeks from referral.

Private enforcement

34 What private causes of action may citizens or other private bodies bring to enforce a healthcare regulation or law?

Other than claims for clinical negligence, the primary route for a private person or entity to enforce a healthcare regulation or law is a complaint to the relevant authority, which will then decide whether to take action. The decision of that authority is subject to judicial review by the courts.

Private enforcement of competition law is a growing area in the UK. It is possible for victims of anti-competitive conduct by healthcare providers to bring claims, either in the CAT or in the High Court, to recover any losses they have suffered.

35 What is the framework for claims of clinical negligence against healthcare providers?

All healthcare providers owe a duty of care to patients. The courts will adjudicate where claims of negligence are made.

To bring a successful claim, a claimant must prove a breach of duty by a healthcare professional (either through an act or omission) and that that breach caused, or materially contributed to, the injury in question. To prove a breach, it must be shown that the defendant acted in a way that was not deemed reasonable by a body of the same professionals: *Bolam v Friern Hospital Management Committee* [1957] 1 WLR 582.

The courts will hold both public and private healthcare providers to the same standard.

The remedy for clinical negligence is damages, which are designed to compensate the claimant for the losses they have suffered and are not punitive in nature. While a court cannot require healthcare providers to change its working practices, any criticism of healthcare providers by the courts is likely to be considered very carefully by the appropriate regulator.

36 How and on what grounds may purchasers or users of pharmaceuticals or devices seek recourse for regulatory and legal infringements?

The system of purchasing pharmaceuticals and devices in the UK is highly complex, but in essence pharmacists purchase pharmaceuticals from wholesalers and are reimbursed by the NHS. If there is a problem with those medicines, pharmacists would have a contractual claim against the wholesaler, and a claim in tort against the manufacturer. The NHS is also likely to have a claim against the manufactuer in some circumstances.

Users of medicines will have a claim against the manufacturer if it is defective and causes them an injury or loss. They may also make a report to the MHRA.

37 Are there any compensation schemes in place?

There is no general compensation scheme, but individual schemes have been set up for particular circumstances. In 2000 it was announced that the government would pay compensation to victims and families of Creutzfeldt-Jakob disease, which can be contracted through defective growth hormones. £67.5 million was committed for the first 250 cases.

38 Are class actions or other collective claims available in cases related to drugs, devices and provision of care?

Yes, in circumstances where a claim gives rise to common or related issues of law or fact the court may make a group litigation order (GLO). The group action rules apply to all areas of law, including healthcare.

The GLO procedure is 'opt-in': it permits persons, or legal entities who are bringing claims individually to have their claims managed together.

There is no certification procedure; rather, the courts impose a cut-off date by which claims must join the GLO. Consequently, there are very often different groups of claims managed under a single GLO.

A notable recent example was a GLO against Transform Medical Group in relation to defective implants used in breast augmentation surgery.

A major reform in this area is expected, through the Consumer Rights Act 2015 (CRA 2015), which enters force on 1 October 2015. This enables collective proceedings to be brought before the CAT, by a defined group, without the need to identify individual claimants.

The CRA 2015 will provide the CMA with the power to grant voluntary redress schemes, under which companies which have breached UK or EU competition law voluntarily agree to compensate those who are harmed by their actions.

39 Are acts, omissions or decisions of public and private institutions active in the healthcare sphere subject to judicial or administrative review following a complaint from interested parties?

Yes, judicial review is available within the healthcare sector, against NHS trusts and regulators such as Monitor and the CQC.

Cases are dealt with by the Administrative Court, a specialist court within the Queen's Bench Division of the High Court of Justice.

A judicial review must be filed promptly, and in any event within three months of the decision or action that is subject to a challenge.

The current test for standing requires the applicant to have a 'sufficient interest' in the matter to which the application relates.

Decisions by public bodies can be challenged on a number of grounds, including where the body does not have the power to make the decision, the decision was irrational, or where the procedure was unfair or biased or in breach of the Human Rights Act 1998.

The court has the power to quash decisions which it finds to have been unlawful, and require them to be reconsidered.

40 Are there any legal protections for whistle-blowers?

Yes. The Public Interest Disclosure Act 1998 incorporated a number of provisions into the Employment Rights Act 1996 which were designed to protect whistle-blowers.

This legislation protects whistle-blowers from detrimental treatment by their employer when they make a 'protected disclosure'. Any claims

Update and trends

The MHRA's stated priorities for 2014-2015 include making regulation more supportive of safe innovation, and introducing a combined reporting system for adverse incidents, medicines, medical devices, blood and counterfeit products. Further cooperation with UK, EU and global partners to prevent counterfeit and substandard products is also expected.

Monitor's regulatory strategy for 2014-2017 includes focusing on improving monitoring powers, in particular through the risk assessment framework, promoting innovation through increased flexibility towards new business models adopted by existing foundation trusts, and increased cooperation with the NHS Providers, the trade body for foundation trusts.

The CQC's 2013-2016 strategy includes a focus on improving inspections, notably through the appointment of a chief director of Hospitals and Social Care and Support.

by whistle-blowers in respect of detrimental treatment must be brought within three months.

41 Does the country have a reward mechanism for whistle-blowers?

Currently the UK does not have a public incentivised whistle-blowing process.

In July 2014, the UK's financial regulators, the Financial Conduct Authority, and the Bank of England's Prudential Regulation Authority, recommended that parliament should not create a programme to reward whistle-blowers, saying that it would cost too much and would undermine companies' in-house whistle-blower programmes.

42 Are mechanisms allowing whistle-blowers to report infringements required?

In recent years, there has been a raft of measures introduced with a view to encouraging, or imposing a responsibility, on NHS staff to voice concerns.

Perhaps most importantly, there is a now statutory duty of candour, imposed under Regulation 20 of the HSCA (RA) 2014. This applies to registered persons when they are carrying out a regulated activity. The CQC can prosecute for a breach of parts 20(2)(a) and 20(2), and proceed with a prosecution without first seeking a warning notice.

In February 2015, the NHS published a report following the Review chaired by Sir Robert Francis QC, into whistleblowing in the NHS, entitled 'Freedom to Speak Up?'. This provided further recommendations for healthcare providers to adopt, in order to create a more open and honest culture in the NHS.

Cross-border enforcement and extraterritoriality

43 Do prosecutors and law enforcement authorities in your country cooperate with their foreign counterparts in healthcare cases?

Yes - in recent years the level of cooperation with prosecutors and law enforcement authorities throughout the world has been on the increase.

A notable example was a 2014 criminal investigation by the SFO and Chinese authorities into GlaxoSmithKline for alleged bribery offences.

44 In what circumstances will enforcement activities by foreign authorities trigger an investigation in your country?

There is no specific mechanism that triggers an investigation in the UK following an investigation in another jurisdiction, but clearly where the UK authorities become aware of possible breaches or offences in the UK (either through information received from a foreign agency, or by a request for assistance) they will be investigated in the normal way.

45 In what circumstances will foreign companies and foreign nationals be pursued for infringements of your country's healthcare laws?

There is no restriction on investigations being limited to UK companies or nationals, and the authorities in the UK are capable of, and regularly do, investigate the activities of foreign companies or nationals provided that the relevant conduct has taken place in the UK.

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