

Competition Law and Procurement in the NHS—Recent Developments

Introduction

The UK Department of Health has very recently responded to a legal opinion, commissioned by the campaigning group 38 Degrees, on competition-related issues arising under proposed reforms to the UK's national health service (the NHS). The changes are those brought about under the Health and Social Care Bill (the Bill) currently before Parliament. The legal opinion (the Opinion)¹ and the Department of Health's response (the Response) debate the application of UK and EU competition law to NHS procurement bodies—including the new clinical commissioning groups to be created under the Bill—as well as the requirement for such bodies to observe EU procurement regulations. The Bill also creates a new competition regulator for the NHS, having concurrent powers to those of the Office of Fair Trading.

In addition, the UK government has made changes—coming into force on 1 October 2011—to the regulations concerning procurement, in order to bring UK law into line with EU requirements.

All of these developments have important implications for pharmaceutical companies, medical device manufacturers, and clinical services providers supplying goods and services to the reformed NHS.

The Application of Procurement Legislation to Clinical Commissioning Groups

The Public Contracts Regulations 2006 (the 2006 Regulations)² apply to all public bodies that act as contracting authorities, including, *inter alia*, government departments such as the Department of Health or discrete operational units of those departments, or corporations or groups appointed to act in a way that meets needs in the general interest and that are financed wholly or mainly, or subject to management supervision, or where more than half the directors or members are appointed by a public body. As statutory public bodies established under the Bill, the procurement activities of clinical commissioning groups³ will be subject to rules on public procurement, where the relevant

¹ The Opinion was given by Stephen Cragg and Rebecca Haynes.

² The Public Contracts Regulations 2006 (SI 2006 No. 5), as amended by The Public Contracts (Amendment) Regulations 2009 (SI 2009 No. 2992) and The Public Procurement (Miscellaneous Amendments) Regulations 2011 (SI 2011 No. 2053).

³ Clinical commissioning groups (CCGs) are statutory corporate bodies with the function of arranging for the procurement and provision of NHS services in a particular area. CCGs will be local NHS organisations encompassing groups of GP practices, nurses, and other healthcare professionals.

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financial thresholds are exceeded.⁴ This will apply to the commissioning of medicines, devices, and clinical services.

Where clinical commissioning groups are established as separate legal entities, each will be considered to be a contracting authority in its own right. In the event that clinical commissioning groups are not established as separate legal entities, but are merely established as part of the NHS, they will be considered to be “discrete operational units” under the 2006 Regulations.

The Opinion argued that the procurement rules would apply to clinical commissioning groups, but that those groups would not be equipped for the regulatory burden that such rules impose. In its Response, the Department of Health acknowledged that the procurements of goods by the NHS has always been subject to the procurement rules, as is the commissioning of clinical services. This includes all clinical services, not only those that are the subject of patient choice though the “Any Qualified Provider” policy.⁵ The proposal of the Bill to transfer significant commissioning obligations from Primary Care Trusts to clinical commissioning groups will not affect the application of the 2006 Regulations. In relation to the procurement of clinical services, the 2006 Regulations impose a lighter touch than for other government departments in respect of their commissioning activities. Health services are classified as “Part B” services. In relation to these services, although the strict procedural rules of the 2006 Regulations do not apply, general procurement obligations regarding transparency, equality, and fairness still do.

There is no disagreement between the Opinion and the Response on the application of the 2006 Regulations. The differences relate to the preparedness of the clinical commissioning groups to comply with the regulatory burden. The Opinion advises that:

The government has simply failed to grapple with the frontline issues in procurement, has wholly underestimated the increasing rather than diminishing complexity in the area and has had no or perhaps little regard to the administrative and financial burdens arising from the regime.

⁴ Essentially where the contract is for a consideration in excess of £156,442. There are also provisions for aggregating contracts all of which are intended to fulfil a single requirement of the contracting authority.

⁵ Under which patients have the right to select appropriately qualified providers of specific services, and not merely accept them from the ones designated by the physician or other healthcare provider.

The Department rejected these criticisms, and intends to bring in sector-specific regulations to be enforced by the newly enhanced NHS body, Monitor—as described in a later section of this Advisory. These will supplement the existing—and continuing—Principles and Rules of Cooperation and Competition, which incorporate the Department of Health Procurement Guide. The 2006 Regulations cannot be affected in a way that entails a departure from the obligations imposed by EU law on public procurement. It is therefore essential that the adoption of sector-specific regulations does not add complexity or legal ambiguity. The 2006 Regulations have already been subject to amendment in 2011 in order to bring them back into line with EU obligations (as described below); any further regulatory churn must therefore be avoided.

The Application of Competition Law to NHS Bodies

UK and EU competition law—on anti-competitive agreements under Article 101 of the Treaty on the Functioning of the European Union (TFEU) and Chapter I of the Competition Act 1998, and on abuse by an undertaking of its dominant position in a market under Article 102 TFEU and Chapter II of the Competition Act 1998—apply only to “undertakings.” The term is not defined in UK statutes or the TFEU, but has a well-established meaning set out in EU case law. It covers “any natural or legal person engaged in economic activity, regardless of its legal status and the way in which it is financed.”⁶ It therefore includes a wide range of entities: companies, firms, businesses, partnerships, sole traders, agricultural cooperatives, charities, nonprofit-making organisations, and (in some circumstances) public entities that offer goods or services on a given market.

The question is therefore whether the clinical commissioning groups to be formed under the Bill will be considered “undertakings.” If they are, the full weight of competition law will apply.

The issue was decided in analogous circumstances by the European Court of Justice (now the Court of Justice of the EU) in the *FENIN* case.⁷ The question considered in *FENIN* was whether a collection of government departments and

⁶ See Case C-41/90 *Höfner and Elser v. Macrotron* [1991] ECR I-1979, [1993] 4 CMLR 306, available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:61990J0041:EN:HTML>, (emphasis added).

⁷ Case C-205/03P, *Federación Española de Empresas de Tecnología Sanitaria (FENIN) v. Commission*.

other public bodies that were responsible for running the Spanish national health system (the SNS) which purchased medical instruments from FENIN were undertakings. The European Commission, the Court of First Instance (now the General Court), and the European Court of Justice all found that the SNS bodies were not undertakings in relation to their management of the public health service.

There were two principles underlying the conclusion of the Commission and the courts that the SNS bodies were not undertakings. First, the characteristic feature of an economic activity (essential to the status of an undertaking) it is the activity of *offering* goods and services on a given market, and not the activity of *purchasing* them. Secondly, the purchase of goods and services must be assessed in light of the subsequent use to which they are put, in order to determine the nature of that purchasing activity. The purchasing function will only give rise to a decision that an entity is an undertaking if the subsequent use of the purchased goods amounts to an economic activity. The Commission and the courts found that the SNS bodies did not pursue an economic activity in their use of the equipment, so their purchase of the equipment cannot comprise the activities of an undertaking.

The SNS was found to operate “according to the principle of solidarity” in managing the health system—because it was funded from social security contributions and other state funding and provided free services to its members on the basis of universal cover. This was not an economic activity.

The *FENIN* case appears to remove doubt about the activities of clinical commissioning groups, in respect of their procurement activities that are intended to enable them to perform their functions within the NHS.

Prior to the *FENIN* case, the UK Competition Appeals Tribunal held, in the *Bettercare* case,⁸ that a health trust was acting as an undertaking when it purchased services from a care home operator and provided care home services itself. It did so because it believed that EU law turned on whether or not the entity was in a position to generate effects that competition law seeks to prevent.

The two cases appear to be at odds. The Opinion commissioned by 38 Degrees places great weight on the earlier decision of the UK tribunal, and decries the possibility

that the Department “places all its proverbial eggs in the basket of [...] FENIN.” It advises that the *Bettercare* decision deployed more sophisticated legal and economic analysis, though it seemingly ignores the legal finding of the Court of Justice of the EU that purchasing for the purpose of providing a noneconomic activity cannot be sufficient to endow a purchasing entity with the status of an undertaking. The Opinion therefore concludes that it is “very far from certain” and “not safe to assume” that *FENIN* will be applied to NHS procurement bodies. It retreats somewhat in a later passage in the Opinion, advising that “there is at the very least a considerable risk [and it] cannot therefore be assumed that competition law does not apply to the NHS system” and finally that “it is likely” that clinical commissioning groups and their constituent members will be regarded as undertakings.

The Department's Response rejects the findings in the Opinion, relying on the principles of *FENIN*, and in particular that clinical commissioning groups are not engaged in an economic activity when they procure goods and services for use in the NHS. The Office of Fair Trading expressed a similar view in 2004, following the Court of First Instance judgment in *FENIN*. In a policy note, the OFT indicated that it was unlikely, in the absence of exceptional circumstances, to take forward cases concerning public bodies which are engaged in a mixture of purchasing and direct provision of goods and services for noneconomic purposes.

In the light of the clear case law in *FENIN*, the Opinion is unlikely to convince courts or competition authorities that NHS Trusts or clinical commissioning groups are acting as undertakings in pursuing their procurement activities. This means that competition law relating to anti-competitive agreements or abuse of dominance will apply only where the entities are engaged in economic activities. This is likely to be truly exceptional in view of the clauses of the Bill that seek to separate the commissioning of health services from their provision. This does not, of course, exclude other remedies where clinical commissioning groups take decisions that unfairly prejudice tenderers. For example, it is possible for commercial providers of clinical services to be members of clinical commissioning groups. Should a commissioning group take a procurement decision that unfairly favoured such a member, the matter could be resolved under the dispute provisions contained in the 2006 Regulations.

⁸ *BetterCare Group Limited v. Director General of Fair Trading* [2002] CAT 7.

A New Competition Authority for the NHS

The Bill proposes to enhance the role of the Independent Regulator of NHS Foundation Trusts. Monitor will become its new statutory name. Under the Bill, the main duty of Monitor in exercising its functions is to protect and promote the interests of people who use healthcare services. It will do this by promoting economic, efficient, and effective services, and by maintaining or improving the quality of the services. It must exercise its functions “with a view to preventing anti-competitive behaviour in the provision of healthcare services for the purposes of the NHS which is against the interests of people who use such services.”

Monitor will become a sector-competition regulator, with the powers conferred on the Office of Fair Trading. It becomes a “concurrent” regulator, meaning that, if it chooses to do so it can displace the powers of the OFT in relation to investigations and decisions on anti-competitive agreements and abuse of dominance under UK and EU competition law. The two statutory bodies are expected to cooperate in the exercise of their respective competition functions and to work together where required. Monitor will also be responsible for ensuring that procurement bodies within the NHS observe their duties under the new procurement regulations to be enacted under the Bill.

Changes to the Procurement Regulations

The Public Procurement (Miscellaneous Amendments) Regulations 2011 (the 2011 Regulations) will enter into force on 1 October 2011. They are intended to bring the 2006 Regulations back into line with EU law following the judgment of the Court of Justice of the EU in the health sector case C-406/08 (the *Uniplex* case).⁹ Regulation 47(7) of the 2006 Regulations currently provides that proceedings for breach by a contracting authority must be brought by the economic operator:

Promptly and in any event within 3 months from the date when the grounds for the bringing of the proceedings first arose unless the Court considers that there is good reason for extending the period within which proceedings may be brought.

The CJEU in *Uniplex* found that UK law was noncompliant for two reasons: (a) the period for bringing proceedings should start to run from the date on which the claimant knew, or ought

to have known, of the infringement, and not from the date on which the infringement occurred; and (b) a national court should not be entitled to dismiss proceedings as being out of time, on the basis of the criterion, appraised in a discretionary manner, that such proceedings must be brought promptly.

Courts in the UK have been observing the *Uniplex* judgment in the interim; the 2011 Regulations bring the regulatory framework into line, and provide as described in the following sections.¹⁰

Time limits

Proceedings must be started within 30 days from the date (date of knowledge) on which the economic operator first knew, or ought to have known, that grounds for starting the proceedings had arisen, unless the Court considers that there is good reason for extending the period, in which case it can be extended by up to three months from the date of knowledge. There is no obligation for proceedings to be brought prior to the end of the applicable standstill period of 10 or 15 days (during which the contract cannot be entered into).

It is essential that economic operators, such as pharmaceutical manufacturers or clinical service providers, act promptly in bringing a claim. The date of knowledge will occur where the economic operator has knowledge (or constructive knowledge) “of the facts which apparently clearly indicate, though they need not absolutely prove, an infringement.”¹¹ Although the court has the power to extend the 30 days to a period of up to three months, there must be good reason for doing so; it would be unsafe to rely on the availability of such extension in the normal course.

Automatic suspension

Under the 2011 Regulations, proceedings will be considered to be started when the claim form is issued, and not—as under the 2006 Regulations—when it is served. However, the claim form must be served within seven days after the date of issue. This restores the effectiveness of the automatic suspension of the tender process. Previously, service was deemed to occur two days after the claim form was delivered, even if delivery was by fax or email. This effectively meant that the contracting authority could enter into a contract immediately after receiving delivery of the claim form, thereby avoiding the automatic suspension of the contract award that was the

⁹ C-406/08, *Uniplex (UK) Limited v. NHS Business Services Authority*, 28 January 2010.

¹⁰ There are transitional provisions where the cause of action arises before 1st October 2011.

¹¹ See judgment of the Court of Appeal in *Sita UK Limited v. Greater Manchester Waste Disposal Authority*, 24 February 2011.

intention of the 2006 Regulations. Under Regulation 14 of the 2011 Regulations, where a claim form has been issued prior to the contract having been entered into, and the contracting authority “has become aware” of the issue and of the fact that it relates to the challenged decision, then the contract cannot be entered into.

Although there is no need to send a letter before action, it is advisable to inform the contracting authority immediately that a claim form has been issued in relation to the relevant decision. If the contract has not yet been entered into (whether or not the standstill period has passed) this will automatically suspend the tender process.

Conclusion

The clinical commissioning groups to be created under the Health and Social Care Bill will be subject to the public procurement requirements of the revised 2006 Regulations, as required by EU procurement law. The NHS reforms do not affect the overriding EU law, which seeks to protect the transparency and fairness of the procurement process. The 2011 Regulations further protect tenderers by making it abundantly clear that a disputed contract award will be automatically suspended on the issuance of a claim form, and not its service. So long as the contracting authority has not entered into the disputed contract, and is aware of the issue of the claim form, the contract may not be entered into until the dispute is resolved. However, this does not mean that competition law—relating to anti-competitive agreements and abuse of dominance—will apply to clinical commissioning groups in the ordinary course. Complaints concerning their conduct should not therefore normally rely on claims based on competition law.

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