CMA Response to the HFEA's Consultation on Modernising the regulation of fertility treatment and research involving human embryos

Introduction

1. The Competition and Markets Authority (CMA) is the UK's principal competition and consumer authority. It is an independent non-ministerial government department and its responsibilities include carrying out investigations into mergers and markets and enforcing competition and consumer law. The CMA helps people, businesses and the UK economy by promoting competitive markets and tackling unfair behaviour. [1]

2. The CMA has a role in providing information and advice to government and public authorities. [2] The CMA's advice and recommendations are made with a view to ensuring that policy decisions take account of the impacts on competition and consumers. The CMA also produces guidance for businesses to clarify their consumer law obligations and promote compliance.

3. The CMA's response to the Human Fertilisation and Embryology Authority's (HFEA) Consultation on 'Modernising the regulation of fertility treatment and research involving human embryos', focuses on areas relevant to the CMA's work in the fertility sector and specifically the consultation section headed 'Patient safety and promoting good practice', questions 13 to 15 and 18 to 19.

4. In summary, the CMA considers the fertility sector to be complex, with a range of factors that can make patients particularly vulnerable as consumers. The focus of the existing legislation in the sector is on the safety and social implications of fertility treatment. The CMA view is that the HFEA's remit and regulatory powers should be updated to also cover the consumer interests of patients. This would include giving the HFEA a greater range of regulatory tools and sanctions so that it has greater flexibility and speed to make rules on standard licence conditions. The power to directly enforce more aspects of its Code of Practice would be

[1] The CMA's statutory duty is to promote competition, both within and outside the UK, for the benefit of consumers.

[2] Under Section 7(1) of the Enterprise Act 2002, the CMA has a function of making proposals, or giving information and advice, 'on matters relating to any of its functions to any Minister of the Crown or other public authority (including proposals, information or advice as to any aspect of the law or a proposed change in the law).'

helpful for protecting consumers, and new sanctions, such as fining powers, would allow the HFEA to take more targeted and effective action when it finds non-compliance. More generally the HFEA should have an explicit duty to protect and ensure fair treatment of patients as consumers.

Background about the CMA's work in the fertility sector

5. In February 2020, the CMA announced it would be undertaking work to develop consumer law guidance for IVF clinics in the UK. At that time there was no guidance on consumer law for the IVF sector and the CMA's initial engagement work had identified a general lack of awareness of clinics' obligations under consumer law. Following discussions with the HFEA, and other stakeholders with knowledge of the sector, the CMA considered that guidance would help improve compliance with consumer law which should help address some of the concerns that have been identified in the sector, such as:

   (a) Patients being unable to make meaningful comparisons between clinics' prices because of the way some clinics present misleadingly low headline prices, which do not include essential elements of treatment.

   (b) Patients being faced with unexpected additional costs during treatment.

   (c) Clinics providing partial or misleading information on their success rates.

   (d) Patients not being properly informed by clinics of the limited evidence base for the benefits of certain add-on treatments increasing the chances of a live birth, or the risk associated with certain add-on treatments.

6. In June 2021, following a public consultation, the CMA published consumer law guidance for clinics in the UK providing self-funded fertility treatment. The main purpose of this guidance is to help fertility clinics understand and comply with their existing obligations under consumer law. Alongside the guidance for clinics, the CMA also published a guide and video for patients, which sets out their rights under consumer law. [3]

7. In November 2020 and September 2022, the CMA published the findings of the qualitative patient research it had commissioned. This research has helped inform the CMA's work in this sector. The purpose of this research was to find out more about:

   (a) The experiences of patients who have paid for fertility treatment (November 2020 research). [4]

   (b) How self-funding patients choose between clinics and treatment options (September 2022 research). [5]

[3] The CMA's guidance for clinics, patient guide and patient video - www.gov.uk/cma/self-funded IVF case page
[4] CMA: Consumer research report - November 2020
[5] CMA: Consumer research report - September 2022

8. When the CMA published its guidance, it said that it would begin a review of UK fertility clinics' compliance with consumer law in December 2021. In September 2022, the CMA completed that review and published a report summarising its findings and setting out a number of recommendations for the sector. [6] The CMA found consumer law compliance issues with the majority of the sample of clinics it had reviewed. The issues found included:

   (a) Concerns with the transparency of clinics' price information for patients in relation to IVF and egg freezing, both at the initial research stage (when patients are comparing clinics) and prior to agreeing to treatment with their chosen clinic.

   (b) Clinics advertising success rate claims, including superiority claims, without clearly identifying the basis of the claims, making it difficult for patients to meaningfully compare success rates between clinics.

   (c) Clinics failing to provide information about the evidence for, or risks associated with, certain treatment add-ons.

   (d) Clinics making claims that link success rates to the use of certain treatment add-ons without any, or adequate, explanation of the basis on which the claims were made.

9. Alongside the compliance review findings report, the CMA wrote to certain clinics setting out the specific compliance issues it had identified with them. These clinics have subsequently made positive changes, including to their pricing practices, such as improving how they provide information about which costs are included in the package price for a cycle of treatment and which additional costs will need to be factored in throughout the patient journey.

10. It was not practical for the CMA to assess all UK clinics, so the review was based on a sample of clinics. Given the size of the sample, it is reasonable to assume that the compliance concerns found during the review apply to UK clinics more widely too. The CMA therefore wrote an open letter to the sector setting out the action it expected them to take in light of its findings. [7]

CMA response to Consultation

11. The CMA's general comments relevant to the HFEA's consultation are set out below in paragraphs 12 to 20. Also set out below, in paragraphs 22 to 26, are the CMA's responses to questions 13 to 15 and 18 to 19, which all fall under the HFEA consultation section headed 'Patient safety and promoting good practice'.

General comments

12. It is important when undertaking any work in this sector to consider the particular

[6] CMA Compliance Review Findings Report
[7] CMA & ASA Joint open letter to fertility clinics

characteristics of the market and the patients who are paying for their treatment. In particular, the CMA notes that:

(a) There are a range of factors that can mean fertility patients are vulnerable to some degree, see paragraph 15.

(b) More patients pay for their fertility treatment than have fertility treatment on the NHS. This is in contrast to many other areas of healthcare where there is more NHS provision than private.

(c) Fertility treatment is generally not covered by private healthcare insurance policies, so patients 'self-pay'. As such there are no intermediaries between the clinics and patients, unlike many other areas of private healthcare. This can be important because insurance providers are likely to have more power and experience in dealing with private healthcare providers than individual patients.

(d) A wide of range of new tests and additional treatments are coming to market on an ongoing basis. These are marketed to self-funding patients and come at an additional cost, even when the evidence base for their value or efficacy is lacking or very limited. It is unlikely that private health insurance providers, if they were present in this sector, would agree to pay for such treatments. Whereas self-funding patients may be more willing to try anything new, particularly when additional tests or treatments are recommended or suggested by a medical professional, even if the value and efficacy of a treatment is lacking or very limited.

(e) For many patients this is not a one-off purchase - most cycles of treatment are not successful, and some patients buy many cycles of treatment.

(f) The fertility sector has its own independent, specialised and experienced regulator, the HFEA, which was set up following the inquiry chaired by Mary Warnock, to consider the unique social, ethical and legal implications of IVF, which published its report in 1984. [8] Whilst the market may have changed since the Warnock inquiry, different challenges are now present.

13. As the CMA has explained above, the fertility sector is a commercialised market where most patients self-fund their treatment. Often patients have no choice but to self-fund, as many local Clinical Commissioning Groups do not fund IVF treatment in their areas, or there may be set criteria for funding which some patients do not meet or have exhausted. [9] In England, where the majority of IVF cycles in the UK take place, more than 65% of patients paid for their treatment. [10] The share of IVF cycles funded by the NHS has not only declined in England, but it has also declined in Wales and Northern Ireland over recent years too. [11]

[8] www.hfea.gov.uk/warnock-report-of-the-committee-of-inquiry-into-human-fertilisation-and-embryology
[9] Such criteria may include, for example, not funding treatment if patients are over a certain age or BMI, already have children or only funding a certain number of attempts at treatment.
[10] As reported by the HFEA: www.hfea.gov.uk/treatments/IVF
[11] www.hfea.gov.uk/research-and-data/fertility-treatment-2019-trends-and-figures

14. As reported in the CMA's compliance review findings report, of the 103 clinics licensed by the HFEA, 59 are privately owned, and nearly three-quarters of all self-funded IVF cycles take place in private clinics.[12] A number of clinics are now private-equity backed or owned. In 2018, eight of the leading clinic groups controlled almost half of the UK market.[13] There have been recent examples of further private equity investment and consolidation in the sector. [14] Clinics are actively marketing their services to attract prospective patients, for example on websites, in local media, at trade shows, and clinic events, and they appear to be competing for patients on price, success rates and the treatments they offer.

15. For patients in this sector, deciding to purchase fertility treatment is a significant decision, both financially and emotionally, and for many people it will be a stressful purchase. It is the CMA's view that most, if not all fertility patients will be vulnerable to some degree due to factors such as:

(a) This is a complex purchase, involving estimations of risk and probability, where outcomes are inevitably uncertain. These are challenging concepts consumers.

(b) By the time patients arrive at a fertility clinic many will have been trying unsuccessfully to have a baby for many months or years. The emotional impact of this on the patient and their partner can be significant.

(c) Many patients will be making repeat purchases because previous cycles of treatment have been unsuccessful. [15] As the CMA's November 2020 patient research and conversations with patient representative groups have highlighted, patients often want to do all they can to increase the chances of having a baby, especially if they have had previous unsuccessful treatment, which may be unexplained, or they think their chances of success are low. In such circumstances, our research indicates they can be more willing to buy treatment add-ons, even where the evidence for their effectiveness is lacking or limited, in the hope this may be the answer to previous failures.

(d) Most patients in the UK are not used to buying healthcare, particularly directly from a provider. [16] The information asymmetries between those providing the fertility treatment and those buying the treatment are generally significant, and patients place a great deal of faith in what they are told by clinics.

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[12] There were 45,007 self-funded IVF cycles in 2019 of which 74% (33,408) took place within private clinics and 26% (11,599) took place within NHS settings. Source data: www.hfea.gov.uk/2021-06- 16-state-of-the-sector-underlying-data.xlsx

[13] Laingbuisson, In Vitro Fertilisation: UK Market Report, May 2018

[14] For example, IVI RMA acquired Create Fertility and abc IVF in 2021. For example, Sale of CREATE Fertility marks biggest deal in UK's IVF sector ever (cityam.com); FutureLife acquired CRGH in August 2022. News story: FutureLife acquires London's largest IVF clinic | ICLG

[15] Some patients, whose treatment has been successful, will also buy further cycles of treatment in the hope they will have more children.

[16] In the fertility sector insurance companies rarely act as intermediaries between patients and healthcare providers.

(e) Some patients have a deference to the medical profession and would not question, or may feel uncomfortable, questioning what they are told or recommended by a medical professional.

(f) A cycle of treatment is expensive, and many patients will pay for multiple rounds if their treatment is unsuccessful. [17] The CMA knows from its November 2020 patient research and discussions with patient representative groups, that cost is an important factor for many patients, but some patients feel reluctant to raise issues of cost with a clinic, fearing it may look like they do not want a baby 'enough' or that they cannot afford treatment.

(g) The CMA knows from its September 2022 patient research that there was a wide variation in how patients had funded their treatment. This ranged from using savings, gifts from parents, loans from siblings, personal loans, credit cards, an inheritance, a redundancy pay-out to re-mortgaging their home, or often a combination of these.

(h) For those patients who would like to compare clinics on price, it is very difficult to do so on a like for like basis due to the significant variation in the treatments and services that clinics choose to include in the price of a cycle of treatment. The CMA has found during its compliance review that several of the treatments and services that some clinics include in their advertised cycle package price, which are very expensive, are not included by other clinics in their cycle price, which makes it difficult to compare clinics' prices. This challenge is compounded is due to the complexities involved, with patients being uncertain about what the treatments are and what treatments they may need. In addition, different clinics use different terminology for the same things, creating potential confusion.

16. The consultation document rightly focusses on the need to protect patients, in terms of patient safety and the standard of care they receive. The CMA believes, given the characteristics of the market and the vulnerability of patients, as set out above, that the sector regulator should also protect the wider interests of patients as consumers – including their commercial interests – and ensure that they are treated fairly and are not left vulnerable to unfair trading practices. There are opportunities in this market to exploit patients, should clinics choose to do so. For example, there have been media reports claiming that patients have been mis-sold treatment add-ons, and that patients are wasting their money on unproven treatments.[18] When the HFEA, together with 10 of the leading professional and patient fertility groups, published a consensus statement on the selling of treatment add-ons in 2019[19], it said it was doing so *'in response to growing evidence of add-ons being offered to patients, without conclusive evidence to date that any of them increase the chance of a*

[17] On average a patient has 2.5 cycles of treatment – data provided by the HFEA.
[18] For example: www.bbc.co.uk/news/wales-60467612, www.dailymail.co.uk/IVF-clinics-selling-ineffectiveadd-treatments-desperate-parents-face-fines and www.bbc.co.uk/programmes/panorama (response of HFEA for Panorama programme: www.hfea.gov.uk/2016-news/hfea-statement-on-fertility-treatment-add-ons)
[19] Treatment add-ons are described on the HFEA's website as '*optional additional treatments … [which] often claim to improve the chances of having a baby (live birth rate) but the evidence to support these claims for most fertility patients is usually missing or not very reliable' (CMA emphasis). Treatment add-ons include genetic tests, surgical interventions, drugs, and equipment.'* www.hfea.gov.uk/treatments/treatment-add-ons

pregnancy, and the fact that many patients feel they must do anything to improve the possibility of success.' [20] There remains a wide divergence of views in the sector about the use and effectiveness of some treatment add-ons.

17. Some treatment add-ons can be particularly expensive, and the prices advertised for such treatments can vary significantly between the clinics that offer them. For example, during its compliance review the CMA looked at a sample of clinics to see whether they offered a selection of treatment add-ons. The CMA saw the following lowest and highest advertised prices for these treatments add-ons:

- Endometrial Receptive Array (ERA) – from £900 to £1,500
- EndomeTrio101 – from £1,450 to £3,100
- Reproductive Immunology (IVIG) – from £1,270 to £2,890
- Assisted Hatching – from £380 to £555
- Endometrial scratch – from £150 to £400

As shown from the prices above, treatment add-ons can add significantly to the overall cost of a cycle of fertility treatment, especially if patients are sold several add-ons.

18. Throughout the CMA's work in this sector, this issue of the marketing and selling of treatment add-ons has been raised many times by stakeholders including practising clinicians, embryologists, fertility counsellors and patient groups. Most recently, this was raised in the roundtables held by the CMA in March 2023. [21] One of the key concerns that has been highlighted is that there is often a significant difference between the advertised package price for a cycle of treatment and what patients ultimately pay for a cycle at some clinics, particularly those that routinely recommend and sell expensive treatment add-ons.

19. The CMA considers that it is important that the HFEA has all the information it needs to protect patients and to help patients make informed choices. To that end, the CMA considers that it is important for the HFEA to have the power to require licensed clinics to provide certain information on a regular and ad-hoc basis. Such a power could be used to obtain important information from each clinic, which is currently lacking, for example:

(a) On the average cost of a cycle of treatment at that clinic.

(b) On that clinic's use of treatment add-ons - how frequently they sell the various treatment add-ons to patients.

20. At the moment it is not known what the average price paid for a cycle of treatment is at clinics. This is information that the CMA considers could be particularly useful for the HFEA, and publishing this information would also be helpful to prospective patients. Firstly, historic average pricing data would help identify if any clinics are routinely charging significantly

[20] www.hfea.gov.uk/press-releases 2019/regulator calls for clinics to be more open about treatment add-ons
[21] These roundtables were held to explore the feasibility of developing a standard approach for what is included in any headline advertised price for a single cycle of IVF.

more than their advertised prices, which in turn may indicate if a clinic is routinely selling treatment add-ons. Secondly, patients would be better informed about the cost of treatment at a particular clinic, which would help them to compare prices before they book and pay for a consultation. The CMA's September 2022 patient research reported that it is at the research stage, when patients are shortlisting clinics and then deciding which clinic to have treatment at, that information about the clinics' success rate, prices and location, are particularly influential. When patients booked an initial paid-for consultation, they already intended that this would be the clinic where they would go on to have their fertility treatment. The vast majority of patients in the research - 43 out of 45 - paid for treatment at the same clinic where they had their first paid-for consultation. So, the information provided by clinics at the early shortlisting stage is key to prospective patients' decision making.

CMA responses to consultation questions

21. **Question 14: To what extent do you agree or disagree that the HFEA should have a broader, more effective range of powers to tackle non-compliance?**

The CMA strongly agrees that the HFEA should have a broader and more flexible range of powers and sanctions at its disposal to help ensure compliance and tackle non-compliance when found. The CMA also agrees that the current threshold for licence removal is a high bar for regulatory action, and that the HFEA should have the power to take earlier, more targeted, regulatory action when non-compliance is found, even if the threshold for licence removal is not met. A lower threshold for action, together with a broader range of sanctions (see answer to Q15 below), would enable the HFEA to take targeted regulatory action in respect of matters affecting patients' decision-making, such as the information provided to them about prices and success rates, as well as matters concerning medical care and treatment. The CMA is of the view that consideration should be given to making more aspects of the HFEA's Code of Practice directly enforceable, making compliance with the HFEA's Code of Practice a standard licence condition, or to incorporating protection of patients' consumer interests into clinics' standard licence conditions, to help ensure patients are treated fairly. This would bring the HFEA's regulatory powers more in line with those of other sector regulators. For example, all gambling licences are subject to the condition that the licensee ensures compliance with any relevant social responsibility provision of a code of practice issued by the Gambling Commission.

22. **Question 15: To what extent do you agree or disagree that the HFEA should have a broader range of powers to impose financial penalties across the sector?**

The CMA has confirmed in response to Question 14, that it strongly agrees the HFEA should have a broader and more flexible range of powers and sanctions at its disposal to help ensure compliance and tackle non-compliance when found.

The CMA also strongly agrees that the range of sanctions available to the HFEA should include the ability to impose financial sanctions. This would bring the HFEA's powers in line with those of other sector-specific regulators, such as the CQC, Ofgem, Ofcom, Ofwat, and the Gambling Commission, all of which have the power to impose financial penalties for breach of sector rules or licence conditions.

The CMA notes that the question refers to a financial penalty ensuring that a clinic would need to improve their standard of care whilst minimally impacting existing patients. The CMA agrees that the ability to impose a fine could be a better and more proportionate way to sanction a clinic. It would also be less likely to negatively impact existing patients, unlike for example if a licence were suspended or revoked, which could interrupt the treatment of the clinic's existing patients.

The CMA strongly believes that the focus of financial penalties should not be limited to the standard of patient care. For example, whilst it would in most cases be disproportionate to consider suspending or revoking the licence of a clinic found to be displaying misleading success rates or misleading pricing information, or failing to provide patients with personalised costed treatment plans in line with the requirements of the HFEA's Code of Practice, a financial penalty could be a useful and proportionate sanction to consider in such circumstances. A financial penalty could also be a valuable tool for repeated or persistent non-compliance, for example if the HFEA were to find frequent misrepresentation of success rates by a clinic, as well as having a deterrent effect when it comes to non-compliance by other clinics.

Other regulators have fining powers and use this sanction. For example, Ofcom has issued fines regarding inaccurate and incomplete information being provided to consumers, Ofgem has issued fines regarding the mis-selling of energy contracts by doorstep salespeople to consumers and the Gambling Commission has issued fines for, amongst other things, social responsibility failures. [22]

23. **Question 16: To what extent do you agree or disagree that there should be an explicit duty on the HFEA and clinics to act to promote patient care and protection?**

The CMA strongly agrees that the Act should have an explicit duty to promote patient care and protection. Furthermore, in the CMA's view, this duty should extend beyond patients' medical care and treatment. It should also cover protecting patients as consumers and ensure that they are treated fairly as consumers.

Treating patients fairly would include, for example, clinics providing clear and easy to understand information to patients (including prospective patients) at the time when they need it, such as pricing information, costed treatment plans, success rate information and information regarding the risks, benefits, and clinical evidence base for treatment add-ons.

The HFEA has undertaken and continues to undertake work to encourage licensed clinics to treat patients fairly. For example:

[22] ofcom-fines-o2-150,000-for-providing-inaccurate-and-incomplete-information; ofgem-fines-npower-mis-selling-energy; www.gamblingcommission.gov.uk/william-hill-group-businesses-to-pay-record

(a) In relation to costed treatment plans, there is guidance in the HFEA's Code of Practice[23] which states that licensed clinics should provide certain information to patients before their treatment starts. The CMA's compliance review findings report recommended that the HFEA makes reviewing costed treatment plans an inspection priority to ensure that clinics provide all patients with the information set out within the HFEA's Code of Practice. [24] However, the guidance in the HFEA's Code of Practice is not mandatory for clinics to follow, so the HFEA is limited in the action it can take if clinics fail to provide this important information to patients.

(b) In relation to treatment add-ons, there is guidance in the HFEA's Code of Practice setting out what information clinics should provide to patients, including evidence of the effectiveness of the relevant add-on and information about the potential risks associated with its use. [25] In addition, there is the consensus statement which sets out principles to prevent the mis-selling of treatment add-ons, and the HFEA's traffic light rating system for treatment add-ons which provides a further resource for patients.[26] This is important, because the selling of treatment add-ons can add significantly to the price patients pay for their treatment. However, neither the guidance in the HFEA's Code of Practice nor the consensus statement are enforceable by the HFEA. Moreover, the HFEA does not monitor the selling of add-ons or whether clinics are following the guidance in its Code or Practice, and so there is very little action it can take if it finds that clinics are not following its Code of Practice guidance, or the voluntary consensus statement.

Patients can be vulnerable in relation to the marketing and selling of treatment add-ons by clinics. Patients, especially those who have experienced multiple unsuccessful rounds of IVF treatment, may be particularly drawn to, for example, any marketing statements or recommendations by clinics that say certain treatment add-ons will or may improve their chance of success. The CMA's November 2020 patient research found that some patients bought treatment add-ons even when sceptical about the benefits, because they feared they would regret not doing so if their treatment was subsequently unsuccessful.

The CMA is of the view that consideration should be given to making more aspects of the HFEA's Code of Practice directly enforceable, making compliance with the HFEA's Code of Practice a standard licence condition, or to incorporating protection of patients' consumer interests into clinics' standard licence conditions, so that the HFEA is better empowered to ensure that patients are treated fairly.

24. **Question 19: To what extent do you agree or disagree that there should be more flexibility for the HFEA to make rules governing the setting of standard licence conditions?**

[23] HFEA.gov.uk/Code of practice 2021 (paragraph 4.11)
[24] See paragraphs 4.62 to 4.65 of the CMA's compliance review findings report – link in footnote 2
[25] HFEA.gov.uk/Code of practice 2021 (paragraphs 4.7, 4.8, 4.9 and 4.11)
[26] www.hfea.gov.uk/treatment-add-ons

The CMA strongly agrees that there should be more flexibility for the HFEA to make rules governing the setting of standard licence conditions. Where there are sector-wide issues there ought to be an effective mechanism by which the HFEA can bring about the desired changes across the sector as a whole.

Currently the HFEA could face individual representations and appeals by multiple clinics in response to a change to licence conditions. This can make it difficult for the HFEA to bring about change across the sector in a timely way. The CMA is aware that other regulators have the power to set rules or licence conditions that apply to the whole sector. For example, the Gambling Commission has the power, following consultation with the regulated sector, to specify conditions be attached to each operating licence or each operating licence **falling within a specified class** (CMA emphasis).[27] In addition, all gambling licences are subject to the condition that the licensee ensures compliance with any relevant social responsibility provision of a code of practice issued by the Gambling Commission.[28]

As noted above in response to Question 16, the CMA's view is that consideration should be given to making more aspects of the existing HFEA's Code of Practice directly enforceable, making compliance with the HFEA's Code of Practice a standard licence condition, or to incorporating protection of patients' consumer interests into clinics' standard licence conditions, to help ensure patients are treated fairly as well as safely. Treating patients fairly would include, for example, providing transparent and comprehensive information to patients (including prospective patients), such as pricing and success rate information, costed treatment and the marketing and selling of treatment add-ons.

The CMA also considers that the HFEA should have the power to introduce new mandatory provisions to its Code of Practice, or to make existing guidance-only elements of its Code mandatory, when this is considered necessary. The HFEA could have a consultation process for allowing such changes to the Code, giving stakeholders the opportunity to comment on their proposed changes. This is important as this is a sector that has witnessed significant change since the legislation was introduced, and innovation can be fast paced. However, the current regulatory framework can make it difficult for the HFEA to respond quickly to changing circumstances or new issues. Currently the HFEA is very limited in what it can do with its Code of Practice. It can introduce new licence conditions or directions without legislation but the former is laborious and open to challenge by individual clinics, and the latter is limited by the legislation. If the HFEA wants to introduce amendments to its Code of Practice, it has to present a new draft to the Secretary of State to lay before Parliament, and this would in any case not enable it to introduce new mandatory provisions that are not based on existing legislation, licence conditions, or general directions.

[27] Gambling Act 2005, s.75(1)
[28] Gambling Act 2005, s.82(1)

25. **Question 20: If you would like to comment further on issues related to patient protection and how the HFEA regulates, please tell us more.**

The CMA would like to re-iterate that it considers the fertility sector to be complex and that there are a range of factors, as set out in paragraph 15, which can make patients particularly vulnerable as consumers.

At the time that The Human Fertilisation and Embryology Act was introduced in 1990, the emphasis was on the safety and social implications of fertility treatment, not on patients' welfare or consumer interests. Since then, this sector has become more commercialised, with clinics competing for patients on price, success rates and the treatments they offer, and many more patients now paying for treatment.

The CMA considers that the complexities and sensitivities of the fertility sector lend themselves to a specialist regulator. The HFEA has built up significant knowledge of the sector, and would now benefit from more flexible powers and tools to help it better protect patients, including their commercial interests.