Guidance for Fertility Clinics on Consumer Law

CMA response to the consultation

15 June 2021
CMA143

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1. Introduction

1.1 This document summarises the main comments made by stakeholders to the Competition and Markets Authority's (CMA) consultation on draft consumer law guidance for fertility clinics in the UK.[1] It also sets out the CMA's response to these comments and, where relevant, the corresponding changes it has made to the final guidance. The final version of the guidance is available on the CMA website.[2]

1.2 Alongside the clinic guidance the CMA is publishing a guide[3] for patients and an accompanying video, to assist patients' understanding and awareness of their consumer rights and the factors to consider when purchasing and undergoing fertility treatment.

Background

1.3 In February 2020 the CMA announced that it was producing guidance to help fertility clinics comply with their existing obligations under consumer law following concerns that clinics may be unaware of their obligations.

1.4 Our engagement with the Human Embryology and Fertilisation Authority (HFEA) and stakeholders, including clinics, the professional bodies and patient representative groups, has highlighted a general lack of awareness of how consumer law applies in the fertility sector and identification of some practices that fall short of consumer law obligations.

1.5 Between 3 November 2020 and 29 January 2021, we carried out a public consultation on the draft guidance. This was published on the CMA website, and subsequently publicised both to, and by, a range of stakeholders in the sector, including the HFEA. Alongside the consultation, we also published the outcome of research we commissioned on the experiences of patients who have paid for fertility treatment, which informed the draft guidance.[4]

1.6 During the consultation period we held four stakeholder events for fertility clinics, patient representatives and other interested parties to further seek views and inform the consultation.[5] We also held bi-lateral meetings, spoke at

[1] www.gov.uk/government/consultations/draft-guidance-for-fertility-clinics-on-consumer-law
[2] www.gov.uk/government/publications/fertility-treatment-a-guide-for-clinics
[3] www.gov.uk/government/publications/fertility-treatment-a-guide-to-your-consumer-rights
[4] www/gov.uk/IVF Research Final Report
[5] Stakeholder events were held virtually on 2 December 2020 and 9 December 2020. Over 60 stakeholders attended those events.

events[6], and held a roundtable with the British Fertility Society's Executive Committee.

1.7 The stakeholders that provided formal written responses to the public consultation are listed at section 3. In all, we received 32 written responses. We would like to thank all respondents for their constructive engagement in this consultation.

Next Steps

1.8 The main purpose of the guidance is to help fertility clinics understand and comply with their existing obligations under consumer law.

1.9 With this in mind, and jointly with the HFEA and the ASA, we have written to fertility clinics drawing their attention to the guidance and setting out our expectation that they will review and, if necessary, make changes to their marketing materials, practices and contracts to ensure compliance with consumer law as soon as possible. The guidance has also been disseminated to fertility clinics via the HFEA and is published on the CMA's website[7].

1.10 Although the guidance is principally for fertility clinics, it and consumer law more generally, also apply to other businesses active in the fertility sector such as sperm banks, egg banks, businesses selling complementary fertility treatments and businesses supplying finance for fertility treatment. We encourage these businesses to ensure that they are complying with consumer law.

1.11 We will be carrying out a review, commencing in December 2021, to assess compliance with consumer protection law across the sector. As part of the review we will analyse information from a range of sources, including from stakeholders such as patient representatives and clinics' websites. Should infringements be identified, the CMA or another consumer enforcement partner[8] may decide to take action, including before the compliance review has concluded. This does not mean that enforcement action must, or will be, taken in every case and decisions will be subject to the CMA's prioritisation principles.[9]

1.12 The ASA has published an enforcement notice alongside the CMA's guidance, which sets out what clinics must do in their marketing of fertility

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[6] These included at the Annual conference of the Association of Reproduction and Clinical Scientists, the British Fertility Society, and the Society for Reproduction and Fertility; Progress Educational Trust's event 'An All-Consuming Problem? How to Protect Patients in the Fertility Market'
[7] Joint letter to the sector (publishing.service.gov.uk)
[8] Such as local authority Trading Standards Services or DETI in Northern Ireland
[9] www/gov.uk/CMA prioritisation principles

treatment to comply with the UK Code of Non-broadcast Advertising and Direct & Promotional Marketing ('the CAP code').[10] The ASA can take enforcement action for non-compliance with the CAP code.

1.13 We will continue to work closely with the HFEA. Where we identify issues that cannot be addressed by consumer law, we may refer these to the HFEA, or others, where such matters fall within their remit.

[10] www.asa.org.uk/resource/enforcement-notice-fertility-treatments

2. Response to the consultation questions

2.1 The CMA's consultation on draft guidance for Fertility Clinics on Consumer Law invited responses to the questions shown in bold below. We have carefully considered all the responses received and the representations made to the CMA as part of the consultation. The CMA's response to the main issues highlighted is included after each question.

2.2 It's also worth noting that a number of consultation responses included points relevant to several of the questions asked. To avoid undue repetition, we haven't repeated every point under every question. Instead, we've described the point under the question to which we think it most closely relates. This is in addition to considering it more generally for all aspects of the guidance.

2.3 As an overarching comment, we have restructured the final guidance into six chapters. In particular, chapter 4 on Treating Patients Fairly in the draft guidance has been separated out into three separate chapters in the final guidance to help improve accessibility. Chapter 4 in the final guidance sets out our views on commercial practices that may be unfair, in particular in relation to meeting the consumer law standard of professional diligence, chapter 5 covers contract terms, and chapter 6 is about complaints handling processes.

Question 1

Does the draft guidance cover all of the important issues around the consumer law practices, policies and terms used by fertility clinics in their dealings with patients? If not, what else should this guidance include and why?

2.4 Most stakeholders made no comment on other consumer law issues that the guidance should include.

2.5 Some stakeholders questioned who the CMA's guidance is aimed at, whether it was only for HFEA licensed clinics, and suggested that the scope of the guidance should be expanded to cover other businesses operating in the fertility sector. For example, businesses offering complementary fertility therapy services were highlighted by some patient representative bodies as a growth area and where there are purported practices that are alleged to infringe consumer law.

2.6 Some stakeholders also thought the guidance should further clarify how consumer law applies to fertility clinics based outside of the UK.

2.7 A couple of stakeholders suggested that the guidance should make reference

to surrogacy with IVF where the ‘consumer’, i.e. the person paying for the treatment, and the ‘patient’, i.e. the person receiving the treatment, are different.

CMA response

2.8 The guidance sets out the CMA’s views on how consumer law applies to clinics operating in the fertility sector. It is primarily aimed at fertility clinics who are providing self -funded fertility treatment to patients in the UK. We have updated the guidance to clarify that this includes clinics that are licensed by the HFEA and clinics (or individuals acting in a self-employed capacity) that offer a satellite service, whereby they carry out aspects of fertility treatment, such as assessment and monitoring, which are not directly licensed by the HFEA. These could be regulated by the CQC in England, Health Improvement Scotland in Scotland, the Health Inspectorate Wales, and the RQIA in Northern Ireland (also see response to question 2 below).

2.9 Our guidance is primarily aimed at fertility clinics. However, UK consumer law applies more widely and also protects patients in their dealings with other businesses active in the fertility sector such as sperm banks, businesses selling complementary fertility treatments and businesses offering different payment options. We have updated the guidance to make clear that patients may interact with and enter into contracts with such businesses and that these businesses will have obligations to provide patients with material information. Some of the examples of practices that could mislead patients outlined in the guidance are also likely to be relevant to other businesses active in the sector too.

2.10 The draft guidance already explained that it, and consumer law more generally, is relevant to clinics based outside of the UK in so far as they are conducting activities in the UK. We have expanded the examples in the final guidance and make clear that as well as overseas clinics needing to ensure that their marketing activities in the UK comply with consumer law, where they are entering into contracts alongside marketing, for example at trade shows, they will also need to ensure that their terms are fair too.

2.11 We have amended the final guidance to include reference to surrogacy with IVF, recognising that the would-be parents are the consumer purchasing the treatment, with rights under consumer law.

Question 2

Paragraph 2.18 of the draft guidance explains that the guidance is aimed at all providers of fertility treatment to patients in the UK, except for the NHS when it

directly provides free treatment in accordance with its statutory duties. The CMA considers that this will include clinicians acting in a self-employed capacity. However, in order to make the guidance as useful as we can, we would find it helpful to hear more about the extent to which, and the circumstances in which, patients contract directly with an individual clinician rather than the clinic.

2.12 Some of the fertility clinics that responded to this question highlighted that there are a variety of contracting arrangements. For example:

- some patients may contract directly with a fertility clinic that is licensed by the HFEA and which provides all of the services.
- some patients may contract directly with a fertility clinic that is licensed by the HFEA but that some aspects of the treatment could be undertaken by a satellite clinic that is owned and operated by the licensed clinic, but is based away from the licensed clinic's primary address.
- some patients may contract directly with a clinic or an independent clinician, that is not directly licensed by the HFEA[11], but that offers a satellite service to carry out aspects of the treatment such as assessment and monitoring. In this scenario the patient transfers to HFEA licensed clinics for licensed services such as egg retrieval and embryo transfer. The patient may have separate contracts with both the satellite clinic / clinician and the HFEA licensed clinic to provide different aspects of treatment.

2.13 Some stakeholders asked for clarification about whether HFEA licensed clinics will be held responsible for satellite clinics' or clinicians' compliance with consumer law, in particular where the satellite clinic or clinicians are not owned or operated by the licensed clinic and which were said to be outside of their control.

2.14 Some stakeholders suggested that the guidance should apply where any provider is charging for any element of fertility treatment regardless of the status of the clinic, i.e. whether it is a private clinic or an NHS clinic. They suggested that in this way, there should be a level playing field.

2.15 We also received some consultation responses asking whether the guidance

[11] Some clinics or independent clinicians may operate under the terms of what are known as "satellite agreements". These mandatory agreements set out the relevant parties' responsibilities under the HFE Act. The HFEA licensed clinic is responsible *inter alia* for ensuring that independent clinicians acting under these agreements comply with HFEA requirements with respect to the provision of information to patients.

could clarify if clinics can charge NHS patients for additional treatments, noting that there is wide variation in practice across the sector.

CMA response

2.16 We have updated the guidance to incorporate the different contracting arrangements we have been told about, as highlighted in paragraph 2.12 above. We have sought to clarify that the guidance is not just aimed at clinics licensed by the HFEA under the Human Fertilisation and Embryology Act 1990. We have updated the guidance to explain that it applies to HFEA licensed clinics and clinics (or individuals acting in a self-employed capacity) that offer a satellite service whereby they carry out activities such as diagnostic testing, agreeing treatment plans and cycle monitoring but which are not directly licensed by the HFEA.

2.17 In response to comments from some stakeholders about whether HFEA licensed clinics are accountable for a satellite clinic's compliance with consumer law, we have clarified in the final guidance that a fertility clinic (regardless of whether it is directly licensed by the HFEA or not) is responsible for ensuring its own compliance with consumer law, even where it is working with or for another clinic.

2.18 We agreed with stakeholder comments that the guidance should cover any clinic providing fertility treatment in return for payment, irrespective of whether it is a private clinic charging for such treatment or an NHS clinic charging for such treatment. We have also further clarified that consumer law would not generally apply in relation to the provision of treatment that is funded by the NHS and which is provided to a patient free of charge, whether by an NHS or a private clinic.

2.19 The draft guidance explained that individuals can be a trader for the purposes of consumer law. This means that clinicians working in a self-employed capacity are subject to consumer law in their own right where they meet the definition of a trader. However, we have included in the final guidance a couple of examples of where self-employed clinicians are likely to be considered a trader.

2.20 In respect of whether NHS clinics can charge NHS patients for additional treatments, it is not within the CMA's remit to comment on the legality of clinics charging NHS patients for add-ons and we are aware that NHS guidance exists on these matters.[12] However, where a patient pays for

[12] Guidance on NHS patients who wish to pay for additional private care (publishing.service.gov.uk)

treatment over and above their free NHS treatment, such as for an add-on treatment, in the CMA's view then consumer law will apply in relation to the self-funded aspect of the treatment.

Question 3

Would it be helpful if the guidance said more on fertility clinics' relationships with third parties, for example partner clinics abroad, third party finance providers, or sperm banks etc. If so, what issues would it be helpful for the guidance to consider?

2.21 Most stakeholders that responded to this question thought it would be helpful for the guidance to further clarify the responsibilities and liabilities for clinics' relationships with third parties.

2.22 We received suggestions that the guidance should clarify:

- who is responsible for information provision where clinics have third party relationships
- that clinics should declare any financial or other incentives for recommending a particular third party – and when and how these declarations should be made
- that where clinics have relationships with third parties that offer multi-cycle packages, unlimited cycle packages, and/or refund programme packages, clinics have a responsibility to tell patients that the finance provider is not their only option.

2.23 But we also heard some views that clinics' relationships with third parties were covered by third party agreements and regulated by the HFEA and as such didn't need to be covered in the CMA's guidance. Specifically, in relation to disclosure of financial interests or incentives we were told that there are already significant rules and/ or guidance from the HFEA and the GMC and that the final guidance should not go beyond existing requirements.

2.24 Some stakeholders also commented that patients may enter into contracts directly with third parties without any involvement of the fertility clinic.

2.25 Where a UK clinic partners with an overseas clinic, several stakeholders highlighted that clarity was needed on:

- who the patient contracts with, for example, whether overseas clinics are subcontractors

- who is responsible for the provision of information
- the differences in laws and regulations, for example in relation to anonymous gamete donation
- responsibility for success rate information, how success rates of overseas clinics are calculated, and whether this is verifiable information
- responsibility for ensuring marketing materials are compliant with consumer law.

2.26 Egg donation was highlighted as a specific example where clarity around third party relationships would be helpful. We were told about different ways patients can obtain donor eggs including where UK clinics partner with third parties in the UK and abroad and the need for patients to be given clear information about the different options.

CMA response

2.27 We have updated the final guidance to further clarify consumer law responsibilities in the context of the myriad of different third party relationships which clinics may have.

2.28 We make specific reference to the fact that that patients may interact with different businesses during the course of their treatment. We have explained that patients may enter into more than one contract for their cycle of treatment and this could be with the same clinic, more than one clinic, or with third parties when purchasing goods or services linked to fertility treatment such as parties that offer multi-cycle packages, unlimited cycle packages, and/or refund programme packages.

2.29 We have clarified that clinics will be responsible for ensuring that all information they provide to patients is compliant with consumer law, including where they are advertising the services of third parties and where they are using information provided to them by that third party.

2.30 We have clarified that where patients contract directly with third parties those businesses have obligations under consumer law to provide material information to patients, and we have given some further illustrative examples in the misleading actions and omissions tables of the different types of information we would expect third parties to provide at the different stages of the patient journey.

2.31 The draft guidance already explained that we consider omitting to declare a conflict of interest or a financial incentive with respect to a treatment, service

or product being offered or recommended is likely to constitute a misleading omission under the CPRs. However, we have added that failure to declare a conflict of interest or a financial incentive as a possible example of a failure to comply with the standards of professional diligences, with specific reference to the GMC's *Good Medical Practice* guidance. This is an example of the fact that existing regulatory requirements inform the standard of professional diligence (see question 8 below).

2.32 That said, professional diligence is but one aspect of consumer law. The guidance already explains the interaction between regulatory obligations and sector-specific regulation, that consumer law sits alongside (i.e. that compliance is in addition to) other sector-specific and general medical professional laws, regulations and standards.

2.33 We have made no comment in the guidance on the contractual relationships between UK clinics, overseas clinics or other third parties as this will be fact specific. However, we have explained more generally that a satellite clinic may be liable under consumer law in its own right, even where it is working with or for another clinic. In respect of the request for clarity where UK clinics have arrangements with overseas clinics, we have clarified the obligations for overseas clinics conducting activities in the UK to comply with the guidance and consumer law more generally.

2.34 In respect of egg donation, the draft guidance already included examples of practices that could mislead patients including advertising donor egg treatment and we have not updated those examples. For example, omitting the fact that the treatment takes place with a clinic abroad under a different regulatory framework (paragraph 3.51(e) of the final guidance) and making false claims about the availability of donor eggs and where these have been obtained from (paragraph 3.53(g) of the final guidance).

Question 4

The draft guidance – see Chapter 3 – sets out the CMA's views on what is likely to constitute 'material information' under the CPRs, by which we mean the information that potential and existing patients need, at certain stages, in order to make informed choices about matters such as which fertility clinic to choose, and what treatments to buy. The information that must be provided according to the CPRs is the information that is necessary for the average patient to make an informed transactional decision, which is distinct from information that is only useful or may be helpful.

Do you agree with our assessment of the information likely to constitute 'material information' under the CPRs? (see paragraph 3.32 of the draft

guidance): in particular:

(i) Is there any information currently included that you do not think constitutes 'material information' and if so why?

2.35 No stakeholder suggested that any of the information that we had assessed as necessary to be provided to patients to allow them to make informed decisions, did not constitute material information. However, we did receive some views on the stage during the patient journey at which the material information should be provided to patients. Most of the comments received were in respect of table 1 at 3.32 of the draft guidance.

2.36 Some stakeholders thought that the material information we had identified was an accurate portrayal of what information should be provided to patients and when it should be provided. Whilst a few raised concerns that the material information envisaged to be provided at stage 1, the research stage, is too detailed and that patients may not have sufficient knowledge to recognise which treatment options are relevant to their individual circumstances. Some stakeholders thought some of the information envisaged at stage 1 would be more appropriate for stage 2, the pre-fertility treatment stage.

2.37 We were asked to consider and clarify specific aspects of the material information, in particular:

- Table 1, paragraph 2 of the draft guidance - what is meant by "what a standard cycle of IVF typically costs"? We heard of clinical differences of opinion about what forms part of a standard cycle of IVF and that it varies on a clinic by clinic basis. For example, that some clinics offer blastocyst culture as part of a standard cycle of IVF, whereas others provided this at an additional cost as needed.

- Table 1, paragraph 3(a) of the draft guidance - the suggestion that clinics should set out at stage 1 "any additional tests, treatments, medication or other services that may become necessary…". We heard that there are potentially an infinite number of tests, treatments, medication or services that a patient could need and this depended on the patient's circumstances. Given this, it could be unhelpful to provide patients with a long list.

- Table 1, paragraph 3(d) of the draft guidance - what is meant by "any significant associated risks" of a cycle of treatment? We heard that at stage 1 patients are unlikely to know whether a particular treatment is relevant to them and as such if the risks are applicable to their individual circumstances. Further to this, that information about risks associated with

treatment is more appropriate at stage 2 where risk discussion and mitigation is said to form part of the consultation.

- Table 1, paragraphs 6 and 10 of the draft guidance - the differences in the success rate information that is required at stage 1 and stage 2 and what was meant by 'own chances of success' at stage 2 of the patient journey?

- Table 1, paragraph 12(b) of the draft guidance - the suggestion that at stage 2 clinics set out all aspects of treatment that a patient may need to pay for on top of the agreed treatment and in what circumstances. We heard that a patient's treatment may change depending on how they respond to medication and it is not possible to set out an indicative price range. We received similar comments in relation to paragraph 3.25 of the draft guidance.

2.38 We were also asked to recognise that many clinics use electronic platforms to provide information to patients.

CMA response

2.39 We have considered the representations that some of the material information that we outlined should be provided at stage 1, the research stage, is too wide or should only be provided at stage 2, the pre-treatment stage, when patients are said to have more knowledge.

2.40 We have updated table 1 of the final guidance, which outlines the material information clinics we consider that clinics should provide at the different stages of the patient journey.

2.41 We have clarified the requirements for clinics to provide patients with material information about the costs of IVF. We have removed the reference to what a standard cycle of IVF typically costs. The final guidance now refers, at Stage 1, to the need to provide material information about the advertised price of treatment including what is included or excluded from any advertised package. We have also clarified that if the cost of medication is additional then a reliable indication of the additional cost should be provided.

2.42 It is important that patients have information that enables them to meaningfully compare clinics' prices. In addition to the changes to the final guidance described in the paragraph above, we have outlined in the accompanying guide for patients the types of things that clinics may include in their advertised package prices to help patients make comparisons when researching clinics.

2.43 In respect of success rate information, we consider that patients should be

provided with this information at both stages 1 and 2. We have amended how the provision of success rate information is described in table 1. In particular, to clarify that the success rate information to be provided at stage 2 is likely to consist of confirmation that the patients' individual chances of success are in line with the average for someone of their age, or better or worse. For the avoidance of doubt, we are not expecting clinics to give patients their own specific success rate percentage.

2.44 Recognising that treatment may change depending on how the treatment cycle progresses, we have updated the final guidance to clarify that we expect clinics to provide patients with material information about the more common and reasonably foreseeable changes to treatment and costs. However, we consider that patients should be able to understand the impact of the potential change, for example, by provision of an indicative cost range for medication or an actual price for a scan.

2.45 We have added electronic platforms to the examples of ways that information is provided to patients in the final guidance.

(ii) **Is there any other information you think ought to be included as constituting 'material information' and if so why?**

2.46 A few stakeholders queried whether we should include additional examples of material information such as the following:

- that patients are entitled to their patient records and any costs associated with obtaining those records.
- a clinic's acceptance criteria for who they will provide treatment to, particularly in relation to comorbidities.
- whether the clinic offers counselling as part of the patient journey[13].
- in relation to egg sharing arrangements – information about the nature of the treatment and the potential impact on the patient.
- in relation to egg freezing – information about success rates, costs and risks.
- information about the quality of donor sperm.

2.47 We also received a few comments about whether we could clarify what

[13] As per the requirements under the HFEA's Code of Practice.

material information should be provided at post-treatment stage. We were also asked to clarify what constituted material information for other types of fertility treatment or subgroups of patients, such as multi-cycle or refund packages and surrogacy with IVF.

CMA Response

2.48 We have carefully considered stakeholder suggestions of other information that should be included in the final guidance as constituting material information. Where appropriate, we've added to Table 1, which describes the material information we consider clinics should provide at each stage of the patient journey.

2.49 We have carefully considered stakeholder suggestions of other information that should be included in the final guidance as constituting material information. We have added as a further example of material information whether counselling (in addition to tests, treatments medication or other services) is included in a package price. We also considered whether the further examples were better suited to descriptions of misleading action or misleading omission, or indeed to other sections of the guidance. With this in mind, we have added to the sections on misleading action/omission examples related to egg sharing arrangements and egg freezing. Providing misleading information about the quality of donor sperm was already included as an example of such practices in the draft guidance and we've retained it in the final guidance. We also thought that failure to offer counselling services merited a further reference in the section dealing with professional diligence (see paragraph 2.82 below).

2.50 We also note in the final guidance that there may be additional stages of the patient journey for some, with further additional information requirements for other types of fertility treatments and patients, and we have provided indicative examples of such material information.

2.51 Lastly, the draft guidance already included reference to a potential post treatment consultation at the end of stage 3 and this reference remains in the final guidance.

Question 5

Are there any important elements of a patient's journey with clinics that we have missed and what do you think the implications of this may be?

2.52 Most stakeholders offered no comment on the patient journey or thought that the patient journey as outlined by the CMA was accurate.

2.53 Some stakeholders suggested that the patient journey is more fluid than we had presented and some noted that the journey is framed as a patient just starting out when they could be further along in the journey. Whilst others suggested that the patient journey could start with a satellite clinic before moving to a HFEA licensed clinic.

2.54 We also received suggestions that the patient journey be extended to include a post-treatment stage for example in relation to the provision of counselling and support in the event of an unsuccessful outcome.

CMA response

2.55 The final guidance is focused on the main stages based upon a cycle of IVF/IUI/ICSI .We consider that the draft guidance already recognised that not all patients will need or want to go through all three stages of the patient journey and we consider that the patient journey may even be circular for some patients. However, we have clarified in the final guidance that there may be other stages of the patient journey for some and additional information requirements.

2.56 As highlighted in paragraph 2.51 above, the final guidance continues to make reference to the post treatment consultation at the end of stage 3 of the patient journey.

2.57 As outlined in paragraph 2.16 above, we have updated the final guidance to clarify that it is aimed at both HFEA licensed clinics and clinics providing a satellite service and as such we do not consider we need to make changes to the patient journey to reflect this further.

Question 6

The draft guidance – see Chapter 3 (paragraphs 3.33 to 3.36) - sets out the CMA's views on the types of business practices that may constitute misleading omissions or misleading actions under the CPRs. Are there any additional examples that would be useful in the guidance?

2.58 We received some suggestions for additional examples of misleading actions or omissions for inclusion in the guidance, including:

- advertising of time-limited or special price promotions when these are not available or are only available to a limited number of patients.
- omitting to provide upfront information about surrogacy options and costs.

- consultants unduly influencing patients' choices of clinics when making recommendations by directing them to their own private clinic without clearly disclosing their interests.

2.59 We also received some conflicting views in relation to the example misleading action outlined at paragraph 3.36b, relating to advertising and selling IVF treatment as 'natural IVF', 'mild IVF', 'IVF light' or similar. Stakeholders have different views on what terminology should be use, with one saying there is no such thing as 'standard IVF' and as such the example provided in the draft is inaccurate and potentially misleading. A couple of stakeholders welcomed the inclusion of this example in the guidance, and one suggested the CMA should go further and include the inappropriate use of such treatments more broadly. All stakeholders did agree though, that all IVF - whether that be 'natural', 'natural modified', 'mild', 'low stimulation' or 'conventional' - involves the same medical procedures, e.g. egg collection, embryology and embryo transfer, with the key difference between them being the amount of medication used to stimulate the ovaries.

2.60 We also heard about additional misleading omissions or actions in relation to the presentation of success rates. Some stakeholders noted the wide range of metrics used across the sector to present rates of success. We received conflicting views on what was considered the most appropriate way of presenting this information.

CMA response

2.61 In response to views received, we have made some changes to the types of business practices that we consider may constitute misleading omissions or actions.

2.62 We also have made clear that in our view some of these practices will be relevant to other businesses operating in the fertility sector, alongside clinics. In relation to the example of omitting to provide full information about multi-cycle packages, this has been expanded to include other types of packages such as unlimited packages and refund programmes that we have been told that some clinics or third-parties they work with offer.

2.63 We have considered the different views received on 'natural' and 'mild IVF' and are aware that this is an area where there are differences in clinical opinion about their merits and how they are marketed to patients. Given the comments received we have amended the final guidance, and now state that we consider it is likely to be a misleading omission to advertise IVF as 'natural' without explaining to patients that it involves the same procedures as 'conventional' IVF.

2.64 The draft guidance already included examples of success rate claims that we consider may constitute misleading actions or omissions and these remain in the final guidance. We cannot under consumer law require success rates to be presented in a particular way or using a particular metric.

Question 7

Chapter 3 of the draft guidance sets out the CMA's views on the application of the CCRs including the information that fertility clinics are required to provide to patients before they enter into a contract with the clinic. The 'pre-contract' information clinics need to provide and how clinics need to provide it will depend on how the contract is entered into with the patient.

(a) Do you agree with our assessment that a patient may enter into more than one contract with a fertility clinic for services (treatment)? (see paragraph 3.39 of the guidance)

(b) Do you agree with our assessment that: (i) a contract for the initial consultation, scans and tests is likely to a 'distance contract'? (ii) a contract for the fertility treatment is likely to be an on-premises contract (unless there is no in person face-to face contact)?

2.65 Most stakeholders offered no comment or agreed with the CMA's assessment that a patient may enter into more than one contract with a fertility clinic. A few stakeholders said that patients may not always enter into a formal contract and that some clinics may not have considered the precise point at which they enter into a contract with a patient.

2.66 As highlighted at 2.38 above, we were also asked to recognise that many clinics use electronic platforms to provide information to patients.

CMA response

2.67 We have made some minor amendments to the final guidance to clarify our views that patients may enter into one or more contracts and that these could be with more than one business and that the CCRs pre-contractual information requirements apply to each contract.

2.68 The draft guidance already included a reference to the fact that contracts can also be made orally, partly in writing and partly orally and implied from the conduct of both the clinic and patient – and this remains in the final guidance.

2.69 In light of the clarifications we have made to the scope of the guidance, we have also clarified that patients may have contracts with the NHS where that

patient is purchasing extra treatment or services on top of their NHS-funded treatment and that the CCRs requirements will also apply in those circumstances.

2.70 As highlighted at 2.45 above, we have added electronic platforms to the examples of ways that information may be provided to patients in the final guidance.

2.71 Lastly, reflecting the comments from stakeholders (summarised at paragraph 2.44) about the difficulties of outlining all aspects of treatment a patient is likely to need at the pre-treatment stage, we have also made changes to the provision of pre-contractual information under the CCRs.

Question 8

In paragraph 4.5 we refer to the existence of sector-specific or relevant medical professional laws, regulations and standards, which are likely to inform the standard of professional diligence in the fertility sector. Please provide views on:

(a) which laws, regulations and standards are especially important and explain your reasons;

2.72 Most stakeholders agreed that the laws, regulations and standards published by the HFEA, GMC and the Health Care Professions Council, as outlined in paragraph 4.5 of the draft guidance, inform the standard of professional diligence in the fertility sector.

2.73 Some highlighted other standards that inform professional diligence including:

- NICE guidelines on 'Fertility problems: assessment and treatment' (2013, updated 2017)
- Policy and Practice Guidelines produced by the British Fertility Society
- Guidelines produced by the Royal College of Obstetricians and Gynaecologists for clinical practice
- The Nursing and Midwifery Code (2018)
- UK Code of Non-broadcast Advertising, Sales Promotion and Direct Marketing (the CAP Code)
- ESHRE Guidelines

(b) the existing sector specific regulations and standards which shouldn't be considered relevant and explain your reasons.

2.74 Some stakeholders said that the HFEA's traffic light system and general guidance with respect to add-on treatments should not inform the standard of professional diligence. This was said to be narrow in scope and did not take account of emerging data. We were told that some clinicians believed that some of the "add-ons" assessed by the HFEA as red[14] may be appropriate and beneficial in certain circumstances. There were some concerns expressed that by offering a 'red' add-on a clinic may be considered not to be complying with the requirements of professional diligence under consumer law.

CMA response

2.75 We have updated the guidance to make reference to other sector specific guidelines. However, the examples outlined in the final guidance are illustrative and there may be other regulations and standards that could be taken into account when determining the standard of professional diligence in the sector.

2.76 We are aware that there are wide and diverging views on add-ons and that this is an area in which the HFEA has an ongoing programme of work. That said, we do consider that the regulations and standards published by the HFEA on add-ons will continue to inform (but may not necessarily be definitive of) the standard of professional diligence under consumer law. Consumer law does not expressly prohibit the promotion or selling of add-on treatments including those rated as 'red' by the HFEA. But we do consider that it is likely to be misleading for clinics to offer, recommend or provide information about add-on treatments but omit to provide patients with information about the HFEA's traffic light system and this example remains as a misleading action in the final guidance.

Question 9

In paragraph 4.7 we provide examples of clinics' commercial practices which may fail to comply with the requirements of professional diligence.

(a) Do you agree that the practices highlighted should be included in the list of examples?

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[14] Under its traffic light system, the HFEA assess an add-on to be red where "there is no evidence from RCTs to show that it is effective at improving the chances of having a baby for most fertility patients".

2.77 Some stakeholders disagreed with some of the examples in the draft guidance of the commercial practices which may fail to comply with the requirements of professional diligence. In particular, some expressed concerns that their clinical judgment should not be constrained by consumer law requirements. For example, we heard that clinicians had differences of opinion on the need and frequency for different types of tests. We also heard that practices on the use of ICSI varies globally and that the CMA's guidance should recognise the innovative nature of the sector.

2.78 Some stakeholders did not agree with the example included in the draft guidance of clinics referring patients to a nutritionist where there is no evidence to support this course of action. Many highlighted the correlation between weight and fertility.

(b) Are there further commercial practices which you think we should add to this list?

2.79 We heard from several stakeholders who provided us with further examples of what they consider to be breaches of professional diligence. These include the following:

- aggressive marketing to persuade patients to purchase treatment without sufficient time to consider the offer. In particular, we were told about 'sharp' practice that occurs at fertility trade fairs.
- for commercial reasons some clinics prescribe patients taking part in an egg donor or egg sharing programme a higher dose of medication than they would have prescribed if the patient were not sharing their eggs, in order to produce more eggs.
- failure to communicate in full the benefits and risks of a treatment, including add-on treatments.

CMA response

2.80 The guidance is not intended to constrain medical judgments but to describe existing mandatory legal obligations, which help ensure that patients are treated fairly given their vulnerable position. We recognise the innovative nature of the sector. The examples of where clinics' commercial practices may fail to comply with the requirements of professional diligence of practices included in the final guidance are indicative. We note in the final guidance that what is considered as professionally diligent may change over time.

2.81 In light of the comments received, we have not included the routine over testing example in the final guidance as we recognise that that this is an area where there is some disagreement between clinicians around what tests are appropriate in what circumstances. We have also removed the referral to a nutritionist example. However, we consider that the routine use of ICSI for all patients is likely to be a practice that may fail to comply with professional diligence at this time and this example remains in the final guidance.

2.82 We have added to the final guidance the examples related to aggressive sales practices and overstimulation of patients participating in an egg sharing programme to the guidance. Given the comments received on other aspects of the guidance as outlined above, we have also added failure to declare conflicts of interest and failure to provide access to counselling services as examples of practices that are likely to fall short of professional diligence.

2.83 The draft guidance already included provision of information about the benefits and risks of treatments, including add-on treatments, as an example of material information and this hasn't changed in the final guidance. Omitting to give information about the risks of and clinical evidence of add-on treatments also remains as an example of a misleading omission in the final guidance.

Question 10

The draft guidance – see Chapter 4 (paragraphs 4.26 to 4.57) – sets out the CMA's view on the examples of contract terms that could be open to legal challenge for potential unfairness under the CRA including terms:

- **allowing a wide discretion to vary the service being provided;**
- **allowing a wide discretion to vary the agreed price (in circumstances where the agreed treatment plan has not changed);**
- **giving you a wide discretion to end the contract;**
- **allowing unbalanced rights to cancellation and refunds;**
- **transferring inappropriate risks to patients;**
- **assigning the contract;**
- **excluding or restricting your liability to your patients.**

(a) Do you agree with the CMA's views on the potential unfairness of the terms listed?

2.84 As highlighted at paragraph 2.65 above, some stakeholders told us that patients may not always enter into a formal contract and that some clinics may not have considered the precise point at which they enter into a contract with a patient.

2.85 The main areas where we received comments in respect of the unfairness of contractual terms were:

Cancellations and Refunds

2.86 We heard that some degree of cross-cost subsidies between patients is built into the pricing structure of a treatment cycle and that treatment not progressing all the way to embryo transfer will have been taken into account in the pricing of a treatment cycle.

2.87 Some stakeholders said that staged refunds after egg collection, for example for failure to fertilise would be too complex to implement in practice. We heard that in these scenarios the preparation and embryology time and consumables costs would be the same as those that made it to embryo transfer.

2.88 Some also mentioned that in circumstances where eggs fail to fertilise there can be increased costs to clinics from the provision of additional follow-up support and counselling, which are not passed on to the patient.

2.89 We heard that requiring clinics to provide a partial refund where no eggs are collected, fertilisation fails, or no embryo transfer takes place could also result in unintended consequences that might not be in the patient's interest. For example:

- clinics may increase package prices.
- there could be more price uncertainty at the start of treatment as clinics may move to charge for each individual aspect of the treatment cycle.
- clinics may refuse to treat patients with poor prognosis to avoid giving a refund.
- clinics may transfer poor quality embryos to avoid giving a refund or transfer of embryos at day two or three, rather than waiting to do a blastocyst transfer to reduce risk that no embryos will continuing developing to blastocyst stage.
- increased use (and costs associated for patients) of ICSI where there is no medical need in order to reduce the chances of a failed fertilisation.
- potential increased risk of ovarian hyperstimulation syndrome if patients are unable to pay for freeze-all cycles (should this be charged separately as a consequence of changes in pricing structure).

2.90 Some stakeholders also drew parallels with NHS funded treatment which is typically considered complete if an egg collection procedure has taken place.

2.91 A few stakeholders also stated that our views on cancellation and refunds terms outlined in the draft guidance didn't recognise how multi-cycle packages worked in practice.

Transferring inappropriate risk

2.92 We heard views that the position outlined in the draft guidance implied that clinics would bear any clinical or logistical risks as clinics were best placed to understand and carry such risks. We were told about some risks which were for clinics to manage such as staffing and equipment but were asked to recognise the probabilistic nature of fertility treatment and that fertility treatment may not be able to continue through no fault of either the patient or the clinic.

Variation of the service

2.93 One stakeholder highlighted that the uncertain nature of fertility treatment meant that it may not always be possible to foresee changes that may subsequently become appropriate.

2.94 Another stakeholder commented that the difficulties in changing clinics once treatment has started puts patients in a vulnerable position, and suggested that any contract terms that permit a wide discretion to vary the service or price are likely to create a significant imbalance to the detriment of the patient.

Price variation

2.95 We were asked to recognise in the final guidance that there can be price increases before the contract is entered into, for example where there is a long delay between the quote given at the pre-treatment stage and the patient deciding to proceed with treatment.

(b) Are there any additional types of fair terms, which should be highlighted in the guidance?

2.96 Stakeholder responses highlighted a number of additional important terms. These included:

- Terms that relate to the costs of accessing third party services, for example if patients need to pay a fee to the clinic to transfer their eggs / sperm to a different clinic;

- Terms that relate to an ongoing financial commitment for the patient following completion of the initial treatment. For example, terms relating to the ongoing storage of eggs or embryos;

- Terms that provide clinics with a wide discretion to delay treatment for an unreasonably long period of time where the patient continues to be bound by the contract; and

- Terms that determine the circumstances under which an egg sharing arrangement will take place.

CMA response

- Cancellations and Refunds

2.97 We have carefully considered the feedback in relation to the potential unintended consequences of the position outlined in the draft guidance and we've clarified and updated this section of the final guidance to focus on where fairness concerns are most likely to arise.

2.98 In doing this, we have set out our views on a range of scenarios. We are aware that there are different practices across the sector as to when clinics offer refunds to patients.

2.99 The final guidance has also been updated to reflect the circumstances in which we consider refunds may be due under multi-cycle programmes as well as single cycle treatments.

- Transferring inappropriate risk

2.100 We have removed this section from the final guidance. However, we have reflected on the points raised and expanded the section which sets out our views on the types of exclusion or limitation of liability terms that are open to challenge to give examples of terms where patients assume risks under the contract.

- Variation of the service

2.101 We recognise that it may not always be possible to foresee changes that may subsequently become appropriate and we have responded to this point in relation to the requirement to provide material information in a timely manner as explained further at paragraph 2.44 above.

2.102 In light of the comment surrounding difficulties in changing clinics once treatment has started, we have amended this section of the final guidance to

clarify that once a patient is bound by the contract, changes to the contract can only be made where there is a specific right to vary the terms of the contract, unless the patient agrees to the changes. We have also introduced some examples of variation clauses that are particularly likely to raise fairness concerns, for example where the variation allows clinics to make changes for their own commercial reasons or to the patient's detriment, as well as the types of terms that are less likely to raise fairness concerns.

- Price variation

2.103 We have amended the final guidance to clarify that price variation terms only apply once the patient is bound by the contract. However, to comply with the pre-contractual information requirements under the CCRs we consider that clinics also need to get the patient to consent to a change.

- Other terms

2.104 In response to comments from stakeholders suggesting additional unfair terms to be included as examples, we have added in the final guidance some of the further illustrative examples referred to at paragraph 2.96 above.

Question 11

Do you agree with the CMA's views on how consumer law applies to a fertility clinic's complaint handling processes and practices? (paragraphs 4.58 to 4.66 refer)

2.105 Most stakeholders either agreed with the CMA's views on how the law applies to a fertility clinic's complaint handling processes and practices or did not answer the question.

2.106 We received a small number of comments that it would be helpful if the guidance could specify which organisations patients can escalate complaints to, if they remain unsatisfied with how a clinic has responded to their complaint.

CMA response

2.107 We have updated the final guidance to make reference to some of the organisations that patients can consider escalating complaints to. Linked to this point, we have also clarified in the patient guide, published alongside the guidance for fertility clinics, patients' rights under consumer law to raise concerns or complaints with their clinic, and possibly to third parties too where they are dissatisfied with the clinic's response.

Question 12

What, if any, aspects of the draft guidance do you consider need further clarification or explanation, and why? In responding, please specify which Chapter and section of the draft advice (and, where appropriate, the issue) each of your comments relate to.

2.108 The majority of stakeholders made no suggestions for any of the aspects of the draft guidance to be clarified, other than those raised in response to specific points, many of which are detailed above.

2.109 We received some comments suggesting that it would be helpful for the guidance to include more examples in respect of issues such as professional diligence and refunds. We also heard comments to the contrary, that the guidance shouldn't attempt to cover every scenario or patient journey given that assisted reproduction is constantly evolving and that there are a range of scenarios for different patients. We were also asked to specifically recognise in the guidance the innovative and fast-paced nature of the sector.

2.110 We received comments from a couple of stakeholders who said our reference to preimplantation genetic testing (PGT) in the draft guidance was inaccurate or imprecise. They requested that when we refer to the PGT-related add-on, we refer to it as PGT-A rather than PGT more generically.

CMA response

2.111 The CMA's guidance for fertility clinics sets out our views on how consumer law will apply to a fertility clinic's terms and commercial practices in relation to the provision of any treatment that is paid for by a patient. It is not intended to be exhaustive and we specifically recognise in the final guidance the innovative nature of sector. However, in response to the request for further examples, we have included additional examples or clarified examples of practices that are likely to infringe consumer law where we consider this will improve clarity for fertility clinics. The changes made are outlined in our responses to the questions above.

2.112 We have clarified the references to preimplantation genetic testing to make specific reference to PGT-A. We note that this is also how it is described in the HFEA's traffic lights for add-on treatments.

Question 13

Overall, is the draft guidance sufficiently clear and helpful for the intended audience?

2.113 Most stakeholders either welcomed the guidance or did not respond to the question.

2.114 Many stakeholders also welcomed the proposed publication of the patient guide citing the importance of patients being aware of, and empowered by, their consumer rights when purchasing fertility treatment. Patients were said not necessarily to think of themselves also as consumers. We were encouraged to draft the patient guide in simple plain English.

2.115 Some stakeholders suggested that fertility clinics should be encouraged to signpost patients to the CMA's guidance in their online materials, complaints procedures, and T&Cs.

CMA response

2.116 We have included a reference at paragraph 1.7 of the final guidance specifically recognising that patients may not always consider themselves as consumers. We have also been mindful of this in developing our guide for patients. The purpose of the patient guide is to make patients aware of their consumer rights and to help empower them to get the information they need to make informed decisions and to help them recognise when they may be treated unfairly. We have sought to make this guide accessible and have also published a video for patients to introduce their consumer rights. We will work with patient representative organisations to ensure that the patient guide gets to patients.

2.117 We consider that it would be good practice for clinics to also make patients aware of the CMA's guidance, for example on websites or other marketing materials, but there is no specific obligation under consumer law for clinics to signpost this in their complaints procedures or T&Cs.

Question 14

Are there any other comments that you wish to make on the draft guidance?

2.118 Some responses to this question related to the timing of the compliance review and clarification of potential enforcement next steps. Some clinic respondents welcomed the six month period between the publication of the final guidance and the launch of the compliance review. Equally, some other stakeholders, particularly those representing the interests of patients, commented that the CMA should begin the compliance review sooner citing potential harm to patients in the interim period.

2.119 Some stakeholders suggested that it would be helpful for the CMA to produce model contract terms for fertility clinics to help drive compliance with consumer law. One stakeholder suggested that the guidance should only focus on contractual matters.

2.120 We were also told about some practices that cannot be properly addressed by consumer law. For example, some stakeholders suggested that there was a need for pricing structures and success rates to be standardised.

CMA response

2.121 We have produced the guidance because we have identified that awareness of consumer law across the sector is low. In the first instance, we want to raise awareness of consumer law and help clinics understand and comply with their existing obligations under consumer law.

2.122 Together with the HFEA and the ASA, we have written to clinics setting out our expectations that they review their commercial practices and terms to ensure compliance with consumer law. We will work with the HFEA and others to disseminate the guidance to clinics.

2.123 As highlighted in paragraph 1.11 above, and in the consultation document[15], we intend to begin a follow-up compliance review across the sector approximately six months after publication of our final guidance. We consider that this is a reasonable period of time for the sector to make any necessary changes to ensure compliance.

2.124 Should serious infringements be identified, after the start but before the conclusion of the compliance review, the CMA or another consumer enforcement partner may decide to take enforcement action then, where this is appropriate in all the circumstances.

2.125 We can take businesses to court to prevent breaches of consumer law, obtain orders for redress, and seek undertakings in lieu of court action. We will work with the HFEA, the ASA, and other enforcement partners such as Trading Standards Services to hold clinics, and other businesses operating in the sector, to account.

2.126 Clinics' obligations under consumer law are not limited to contractual matters and as such the final guidance continues to give examples of unfair commercial practices, as well as contractual terms that we consider may be

[15] www.gov.uk/government/consultations/draft-guidance-for-fertility-clinics-on-consumer-law

unfair.

2.127 We note the requests for the CMA to produce model contract terms. However, we consider that this is outside the remit of our consumer law guidance and we have no specific statutory function to provide model contact terms. That said, we have provided within our guidance both examples of contract terms that are more likely to be fair and thereby to comply with consumer law, as well as examples of contract terms which are more open to challenge for being unfair. We consider that clinics are best placed to assess the appropriateness of their own terms.

2.128 In respect of practices that cannot properly be addressed by consumer law, we will be engaging with the HFEA and others as part of their wider role in regulating and/ or developing laws or rules for the sector.

3. List of respondents

Stakeholders that submitted a written response to the consultation:

Assured Fertility
Bourn Hall
British Pregnancy Advisory Service
CARE Fertility
Cooper Genomics
CREATE Fertility
Department of Health Northern Ireland
Engaged MD
The Evewell
Fertility Network
General Medical Council
International Society for Mild Approaches in Assisted Reproduction (ISMAAR)
Leeds Fertility, Seacroft Hospital Leeds
Leicester Fertility Centre
The Lister Fertility
Manchester Fertility
Nuffield Council on Bioethics
Nottingham University Hospital
Progress Educational Trust (PET)
Royal College of Obstetricians and Gynaecologists
Royal College of Nursing
Surrogacy UK
Uberbarrens Club
XY Fertility

Combined response from Access Fertility, David Ogutu - Herts & Essex Fertility, Natalie Silverman - a fertility podcaster, James Lawford Davies - Hill Dickinson LLP & James Nicopoullos -The Lister

Joint response from - Professor Peter Braude, King's College, London; Professor Frances A Flinter, Guy's and St Thomas' NHS Foundation Trust; Professor Caroline Mackie Ogilvie, Guy's and St Thomas' NHS Foundation Trust

Academics:
Dr Annette Thwaites, Institute for Women's Health, University College London
Dr Minyan Zhu, University of Reading

4 individuals