

# Consumer law compliance review of fertility clinics

Findings report

# © Crown copyright 2022

You may reuse this information (not including logos) free of charge in any format or medium, under the terms of the Open Government Licence.

To view this licence, visit www.nationalarchives.gov.uk/doc/open-government-licence/ or write to the Information Policy Team, The National Archives, Kew, London TW9 4DU, or email: psi@nationalarchives.gsi.gov.uk.

# **Contents**

|    |   | Page |
|----|---|------|
| 1. | Executive Summary   | 2    |
| 2. | Introduction  | 11   |
| 3. | The Review  | 18   |
| 4. | Price Information   | 22   |
| 5. | Success Rate Information                                      | 45   |
| 6. | Information about the benefits and risks of treatment add-ons | 60   |
| 7. | Contract Terms  | 73   |
| 8. | Complaints  | 84   |
| 9. | Summary of recommendation and next steps                      | 90   |

# 1. Executive Summary

- 1.1 This report sets out the findings from our review of fertility clinics' compliance with consumer law. We summarise:
  - Our **key findings** in paragraphs 1.21 to 1.23 (UK clinics' practices), 1.31 to 1.32 (overseas clinics' practices)
  - **Positive changes** made by the UK clinics we subsequently contacted, in paragraph 1.27
  - Our recommendations, in paragraph 1.36
  - Our proposed **next steps**, in paragraph 1.37.

# CMA consumer law guidance for clinics

- 1.2 In June 2021, following public consultation, the CMA published consumer law guidance ('the Guidance') for clinics providing self-funded fertility treatment. Alongside the Guidance we also published a guide and video for patients on their consumer law rights.
- 1.3 We developed the Guidance as we had identified concerns in the fertility sector, and we considered that increased compliance with consumer law should help address these. These issues included patients facing unexpected costs as they went through treatment, and patients being unable to make meaningful comparisons between clinics because of the way some clinics were presenting misleadingly low headline prices, or misleading or partial information on success rates. Our discussions with stakeholders had also revealed a general lack of awareness among clinics that consumer law applies in the sector. The aim of the Guidance was to help clinics understand and comply with their obligations under consumer law, in turn protecting patients' consumer rights.<sup>1</sup>
- 1.4 When we published the Guidance we said that we would begin a review of UK fertility clinics' compliance with consumer law in December 2021. We have now completed that review, and this report summarises our findings. It also sets out a number of recommendations to the sector, as well as what we plan to do next.

<sup>&</sup>lt;sup>1</sup> At the same time as we published our Guidance, the Advertising Standards Authority (ASA) also issued an Enforcement Notice to the sector, which provides guidance on the rules when advertising IVF treatment. Fertility-Treatments-Enforcement-Notice-FINALPDF.pdf (asa.org.uk)

# What the CMA's review of compliance has involved

- 1.5 Our review has focused on IVF and egg freezing treatment, and the information clinics provide to patients in relation to price, success rates and treatment add-ons. It has also considered the fairness of clinics' contract terms and complaints handling practices.
- 1.6 We carried out a review of publicly available information on the websites of a sample of UK clinics offering self-funded treatment. This included clinics licensed by the Human Fertilisation and Embryology Authority (HFEA), both private and NHS, as well as "satellite clinics", which are not directly licensed by the HFEA.<sup>2</sup>
- 1.7 We also conducted more detailed reviews on a smaller sample of clinics. These detailed reviews involved assessing information publicly available on the clinics' websites, and also clinics' standard patient information and contract terms which we had requested directly from them. The clinics that formed part of these detailed reviews together represent a significant proportion of IVF provision in the UK; they accounted for 42% of self-funded IVF cycles in the UK in 2018.
- 1.8 We also assessed the websites of a small number of overseas clinics that market their services to UK patients, and attended the 2022 Fertility Show and reviewed the information we collected from the exhibitors.
- 1.9 We commissioned qualitative patient research to shed further light on how self-funding patients choose between clinics and treatment options.
- 1.10 We also compared the prices charged by a sample of clinics for a cycle of IVF treatment, along with the treatments and services they include in, and exclude from, their cycle package price.

# The fertility sector: a commercialised market where most patients self-fund their treatment

1.11 Most UK patients now self-fund their IVF treatment. In England, where the majority of IVF cycles in the UK take place, more than 65% of patients self-fund.<sup>3</sup>

<sup>3</sup> In vitro fertilisation (IVF) | HFEA

<sup>&</sup>lt;sup>2</sup> The HFEA can inspect a satellite clinic. However currently the responsibility for ensuring the satellite clinic complies is on the Person Responsible at the HFEA licensed clinic, which performs the licensed activities on behalf of the satellite clinic. This is managed through a third-party agreement.

- 1.12 Fertility treatment is expensive. According to the HFEA, a single cycle of IVF costs around £5,000 on average, but they also say that prices can vary considerably. We are aware of single cycles of treatment costing patients in the region of £20,000 once costs not included in a cycle package price, such as initial investigations, medication and treatment add-ons, are added in. However, no information is collected from clinics on what patients in the UK have actually paid for their treatment. So it is not currently known what the average price paid for a cycle of treatment is, or the extent to which this varies between clinics.
- 1.13 The fertility sector is now a commercialised market: 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.<sup>5</sup> A number of clinics are now private-equity backed or owned. In 2018, eight of the leading clinic groups controlled almost half of the market.<sup>6</sup> There has been some recent examples of further private equity investment and consolidation in the sector.<sup>7</sup>
- 1.14 Patients in most parts of the UK have a range of clinics to choose from, with the highest concentration of clinics in London, where there are 25 licensed clinics offering treatment.
- 1.15 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.

# Key findings from the patient research

1.16 Although fertility treatment is expensive, the self-funding patients in our latest patient research came from a range of socio-economic backgrounds and there was wide variation in how they 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.

<sup>&</sup>lt;sup>4</sup> In vitro fertilisation (IVF) | HFEA

<sup>&</sup>lt;sup>5</sup> 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: https://www.hfea.gov.uk/media/1whdur0z/2021-06-16-state-of-the-sector-underlying-data.xlsx

<sup>&</sup>lt;sup>6</sup> Laingbuisson, In Vitro Fertilisation: UK Market Report, May 2018

<sup>&</sup>lt;sup>7</sup> 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

- 1.17 Our patient research also found that most patients buying fertility treatment for the first time carried out a shortlisting process, primarily online using clinic websites. For most patients this shortlisting process involved weighing up three main factors: clinics' location, prices and success rates.
- 1.18 The research found that the stage at which price had the most impact on patients' decision-making was early on in their consumer journey, when they were researching and shortlisting clinics. For the vast majority of patients, their first paid-for consultation at a clinic was not used to decide if a specific clinic was right for them, as they tended to have already made the decision about where they wanted to buy treatment from by this point. Instead, initial consultations were used to discuss treatment options.
- 1.19 Among those patients who were actively considering where to have treatment, (i.e. patients buying treatment for the first time as well as those who were not continuing with further treatment at a clinic they had used previously), success rate information was important for the overwhelming majority, and it was used to guide final decision-making around which clinic to buy treatment from.
- 1.20 The findings of this patient research highlight the importance of clinics providing clear and transparent information, particularly regarding their prices and success rates, upfront. It is especially important that clinics provide this information on their websites, where the vast majority of patients look when they are comparing, shortlisting and ultimately choosing a clinic.<sup>8</sup>

# Key findings from our reviews of clinics' compliance

#### Findings from our review of UK clinics

- 1.21 Among the sample of clinics we reviewed, we found a mixed picture in terms of compliance with consumer law. For a small minority of the clinics we reviewed we found no compliance concerns in any of the areas we assessed.
- 1.22 Positively we found that some clinics had made improvements since we published our Guidance and the Advertising Standards Authority published its Enforcement Notice. We could also see that some clinics were continuing to make changes during the course of our reviews.

<sup>&</sup>lt;sup>8</sup> We have published the report summarising the patient research alongside this Findings Report on the Selffunded IVF: consumer law guidance page.

- 1.23 However, we found compliance issues with the majority of the clinics we reviewed, albeit that in some cases these concerns were relatively minor. The concerns we identified with some clinics included:
  - 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;
  - clinics advertising success rate claims, including superiority claims, without clearly identifying the basis of the claims, making it difficult for patients to meaningfully compare between clinics;
  - clinics making success rate claims based on incorrect or out of date information, and creating a misleading impression about the clinic's more recent performance by implying that it is more impressive than it is;
  - clinics failing to provide information about the evidence for, or risks associated with, certain treatment add-ons;
  - 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;
  - examples of potentially unfair terms.
- 1.24 During our review we also found that the vast majority of HFEA-licensed clinics do not subscribe to independent Alternative Dispute Resolution (ADR), so very few patients can access an ADR scheme if they have a complaint that they cannot resolve with a clinic.
- 1.25 Having reviewed a sample of clinics in more detail, we wrote to certain clinics setting out the specific compliance issues we had identified with them. We told the clinics that we expected them to review their practices and contract terms and make appropriate changes to ensure their compliance with consumer law.
- 1.26 We are pleased to note that all the clinics we contacted have subsequently made changes to address compliance concerns we highlighted to them. We welcome the constructive approach generally adopted by clinics. We are continuing to engage with some of the clinics to resolve a small number of outstanding issues.
- 1.27 Examples of positive changes made include UK clinics:

#### Price

- being more transparent about the costs that patients will incur before a cycle of treatment can begin;
- providing clearer information about what they include in the package price for a cycle of treatment, and what they exclude;
- providing information about the price of essential elements of treatment which are excluded from the treatment package price, such as medication and blood tests;
- displaying clearer price information about the future costs associated with IVF and egg freezing treatment;
- providing more accurate, personalised price information following the initial consultation.

#### Success rates

- providing clearer information about the measures that have been used to calculate their success rates;
- removing from their websites success rates which are based on incorrect information or appeared to exaggerate the clinic's performance;
- removing from their websites unsubstantiated success rate claims, such as superiority claims.

#### Treatment add-ons

- updating webpages to provide additional information so that the potential benefits and risks of certain treatment add-ons, as well as the views of the HFEA, are more clearly explained and signposted;
- providing clearer information about the basis for any claims made that link the use of certain treatment add-ons to successful treatment outcomes.

#### Contract terms

- introducing contracts and sets of terms for their patients, where none had existed previously;
- amending their terms to better reflect patients' statutory rights under consumer law.

- 1.28 It was not practical for us to assess all UK clinics, so we have based our review on a sample of clinics. Given the size of the sample, it is reasonable to assume that the compliance concerns we found during the review apply to UK clinics more widely, and that, as a result, some further clinics will need to make changes to their practices and terms.
- 1.29 We were also not able to review all parts of a patient's journey with a clinic.

  Most notably we were not able to listen to the information that clinics provide to patients during private consultations. However, all clinics need to ensure they are complying with consumer law during these interactions with patients.
- 1.30 We have today written an Open Letter to clinics to draw their attention to the compliance concerns we found during the review. We expect clinics to review their information, practices and contract terms and take the necessary action to ensure compliance. A copy of this letter can be found on the CMA's webpages.<sup>9</sup>

#### Findings from our review of overseas clinics

- 1.31 Our preliminary review of overseas fertility clinics' websites found that clinics tended to provide less information on price and treatment add-ons than UK clinics. Where overseas clinics did provide price information, this tended to be little more than a headline cycle package price, with essential costs, such as medication and blood tests, not mentioned at all.
- 1.32 Overseas clinics' success rate claims often failed to provide important information, such as which group (or groups) of patients the rate applied to, or which measure had been used to calculate the rate. This can make it impossible for patients to know whether they are comparing clinics' success rates on a like-for-like basis. Furthermore, unlike in the UK, in many countries success rates are not independently verified, making it difficult for us or patients to check the accuracy of any success rate claims.

# Key findings from our comparison of clinics' IVF cycles

1.33 Our analysis of a sample of 12 London<sup>10</sup> clinics revealed significant differences between what clinics include in their package for a single cycle of

<sup>&</sup>lt;sup>9</sup> Self-funded IVF: consumer law guidance case page

<sup>&</sup>lt;sup>10</sup> We know from our consumer research that clinic location, along with price and success rates, is an important factor for patients when choosing a clinic. We therefore compared clinics based in the same region to try and best replicate the start of a patient journey. London was selected as it incorporated a wide range of clinics offering self-funded treatment and a large number of self-funded IVF cycles are carried out in London: 17,019 in 2019 - HFEA Fertility treatments 2019 trends and figures

- IVF. This variation is likely to make it very difficult for patients to compare clinics' prices when shortlisting clinics.
- 1.34 Notably our analysis also showed that for some clinics there is a very large difference between their headline package price for a single cycle of IVF and the total cost to patients (excluding medication) once the cost of excluded elements of treatment are added in. Ultimately a significant proportion of patients will need to have and pay for these excluded elements of treatment. Indeed, almost all patients will need to pay for some of them. The difference between the headline package price and the price to patients when these additional elements of treatment were included ranged from £0 and £2,975, with the total price of a single cycle ranging from £4,200 to £7,085 (excluding medication).
- 1.35 It is our view that more consistency in (a) what is included in the price of a single cycle package of IVF, and (b) how additional key costs are presented alongside this cycle package price, would allow patients to compare clinics' prices more effectively.

# **Recommendations and next steps**

- 1.36 Summary of recommendations:
  - The CMA recommends that all clinics read this Findings Report and review their information, practices and contract terms in the light of the various examples of potential non-compliance that we highlight. Clinics should also ensure that their information and commercial practices during the parts of the patient journey that we have not been able to assess are compliant with consumer law. They should read our Guidance alongside this Report, and take any corrective action necessary, as a matter of priority. Failure to comply with consumer law could result in the CMA, or others, taking enforcement action.
  - We recommend that the HFEA makes reviewing costed treatment plans an inspection priority, to ensure that clinics provide all patients with a costed treatment plan that includes all the information set out in the HFEA's Code of Practice.
  - We recommend the HFEA encourages all licensed clinics to join an independent ADR scheme, as the CQC does. We further recommend that the HFEA considers whether membership of an ADR scheme could be incorporated into their Code of Practice.

We recommend that clinics and other key stakeholders work with the CMA
to explore the feasibility of developing a standard approach for what is
included in the headline price for a single cycle package of IVF. To be clear
this is about the presentation of price information to help patients
meaningfully compare clinics' prices. It is not about the prices clinics charge
or any form of price regulation.

## 1.37 Next steps:

- The CMA will share this Findings Report with key stakeholders, including the HFEA, Department of Health and Social Care, the General Medical Council, and the professional bodies in the fertility sector.
- We plan to hold roundtable discussions with clinics and other key stakeholders in Autumn 2022 to explore the feasibility of developing a standard approach for what is included in the headline package price for a single cycle of IVF, as well as a consistent approach to providing price information for any key aspects of treatment not included in the standard package for a cycle.
- We will write to overseas clinics that advertise to UK patients, to set out their consumer law obligations and the findings of our review.
- We will respond to the HFEA's consultation on legislative reform. We
  consider the HFEA's current toolkit is not sufficiently flexible, particularly
  given that this is a commercialised and competitive sector. We agree with
  the HFEA that a wider range of directly enforceable sanctions, such as
  financial penalties, should be considered. Such sanctions are likely to be
  helpful for targeting clinic practices which can harm the financial interests of
  fertility patients, such as those outlined in this report.

# 2. Introduction

## **Background**

- 2.1 This report sets out:
  - the background to the compliance review, which began in December 2021;
  - the purpose of the compliance review and what it involved;
  - the review findings, in particular examples of the positive changes made following the publication of the CMA's Guidance and the areas where the CMA has identified ongoing concerns;
  - action taken by the CMA and next steps.
- 2.2 This report should be read in conjunction with the CMA's Guidance for Fertility Clinics (the Guidance).<sup>11</sup>
- 2.3 For the purposes of this report, and the Guidance, where we refer to clinics this includes:
  - clinics that are licensed by the HFEA under the Human Fertilisation and Embryology Act 1990 (the HFE Act); and
  - clinics that are not directly licensed by the HFEA, but which offer a satellite service whereby they carry out aspects of fertility treatment with patients, such as assessment and monitoring (sometimes referred to as "satellite clinics").

# CMA's mission and powers

- 2.4 The CMA is the UK's primary competition and consumer authority. Its objective is to make markets work well for consumers, businesses and the broader economy.
- 2.5 The CMA has a range of consumer powers to tackle practices and market conditions that present challenges for consumers and hinder their decision making. This includes powers to protect consumers from unfair contract terms and unfair commercial practices. As part of this role, the CMA also produces

<sup>&</sup>lt;sup>11</sup> A guide for Clinics - GOV.UK (www.gov.uk)

- guidance for businesses to clarify their legal obligations and promote compliance.
- 2.6 In June 2021, following engagement with the sector and public consultation, the CMA published consumer law guidance for fertility clinics. The purpose of the Guidance is to help fertility clinics understand and comply with their obligations under consumer law.
- 2.7 The main consumer protection legislation applicable to our Guidance for Fertility Clinics, and to the compliance review, is:
  - The Consumer Protection from Unfair Trading Regulations 2008 (CPRs).
  - The Consumer Contracts (Information, Cancellation and Additional Charges) Regulations 2013 (CCRs).
  - Part I and II of the Consumer Rights Act 2015 (CRA).

# Background to the review

- 2.8 We developed the Guidance for clinics because we had identified from media reports, HFEA patient research, and reviews of clinic websites, a number of clinic practices that may prevent or inhibit patients from making informed choices. Our discussions with stakeholders had also revealed a general lack of awareness that consumer law applies in the sector.
- 2.9 At the same time as publishing the Guidance in June 2021, together with the HFEA and ASA we wrote a joint letter to licensed clinics providing self-funded treatment, directing them to read the Guidance and to review their practices and terms to ensure that they comply with consumer law. The joint letter encouraged clinics to share the Guidance with any other businesses that they work with in the sector. A copy of the joint letter was published on the CMA's webpages.<sup>12</sup>
- 2.10 Alongside the Guidance for clinics, the CMA produced a video and a guide for patients on their consumer rights when buying fertility treatment. <sup>13</sup> The CMA also participated in some webinars and events to disseminate the Guidance.

<sup>&</sup>lt;sup>12</sup> Joint letter to the sector (publishing.service.gov.uk)

<sup>&</sup>lt;sup>13</sup> A guide to your consumer rights - GOV.UK (www.gov.uk) and Fertility Treatment: a guide to your consumer rights

2.11 When we published the Guidance in June 2021, we said we would carry out a review of compliance in six months' time. The CMA began the review as planned in December 2021 and we are now reporting our findings.

#### The sector

- 2.12 Fertility treatment encompasses a range of treatments, including IVF, intrauterine insemination (IUI) and fertility preservation. Every year around 70,000 cycles of IVF treatment, around 5,700 cycles of IUI and just over 2,000 egg freezing cycles take place in the UK.<sup>14</sup> In addition to this, an unknown number of UK patients go overseas to have fertility treatment.<sup>15</sup>
- 2.13 The UK fertility market is worth around £320 million annually and has enjoyed steady growth over recent years of around 3% per year, accelerating to 4.5% more recently. 16
- 2.14 Fertility clinics in the UK need a licence from the sector regulator, the HFEA, to provide fertility treatment, store eggs, sperm, and embryos, and to carry out embryo testing. The HFEA's powers are derived from the HFE Act. In 2020/21, 103 clinics were licensed by the HFEA to provide fertility treatment.<sup>17</sup> There are also an unknown number of satellite clinics (or clinicians acting in a self-employed capacity) which are not directly licensed by the HFEA.<sup>18</sup>
- 2.15 The sector has changed significantly since the HFEA was established 30 years ago. The HFEA has said that it believes that the HFE Act should be modernised. <sup>19</sup> This is now a commercialised market. A large number of clinics are equity backed or owned, and many clinics are part of wider groups. In 2018 eight of the leading clinic groups controlled almost half of the market. <sup>20</sup> There have been some recent examples of further private equity investment <sup>21</sup>

<sup>&</sup>lt;sup>14</sup> In 2019 there were 69,000 IVF cycles, 5,700 IUI cycles and 2,377 egg freezing cycles. Figures include both NHS-funded and self-funded treatment. HFEA, Fertility trends 2019: trends and figures, May 2021. In 2020 nearly 60,000 cycles of treatment took place during the pandemic – a decrease of 20% from 2019. HFEA, Impact of Covid-19 on Fertility Treatment 2020, May 2022.

<sup>&</sup>lt;sup>15</sup> The European Society of Human Reproduction and Embryology (EHSRE) in 2017 estimated that around 5% of fertility care in Europe involves cross-border patients. EHSRE says the full extent of cross border reproductive care in Europe is not fully known as national treatment agencies may not record the patient's country of origin, only treatment cycles. https://www.eshre.eu/-/media/sitecore-files/Press-room/Resources/1-CBRC.pdf?la=en&hash=8AFAEF005EC048226FC6EC1037BEE491209B6B67

<sup>&</sup>lt;sup>16</sup> Laingbuisson, In Vitro Fertilisation: UK Market Report, May 2018.

<sup>&</sup>lt;sup>17</sup> HFEA, State of the Fertility Sector 2020/21, November 2021.

<sup>&</sup>lt;sup>18</sup> Satellite clinics that are not HFEA licensed but undertake aspects of fertility treatment such as diagnostics and treatment plans may be registered with the Care Quality Commission in England for the regulated activities of Treatment, Disease, Disorder or Injury and Diagnostic and Screening Procedures.

<sup>&</sup>lt;sup>19</sup> The HFEA 30 years on - what needs to change? | HFEA

<sup>&</sup>lt;sup>20</sup> Laingbuisson, In Vitro Fertilisation: UK Market Report, May 2018.

<sup>&</sup>lt;sup>21</sup> For example, IVI RMA acquired Create Fertility and abc IVF in 2021 and Sale of CREATE Fertility marks biggest deal in UK's IVF sector ever (cityam.com)

- <sup>22</sup> and consolidation in the sector.<sup>23</sup> Of the 103 clinics licensed by the HFEA 59 are privately owned.<sup>24</sup> Many NHS trusts also offer self-funded fertility treatment, but nearly three quarters of all self-funded IVF cycles take place within private clinics.<sup>25</sup>
- 2.16 Most patients in the UK self-fund their fertility treatment.<sup>26</sup> In England, where the majority of IVF cycles in the UK take place, more than 65% of patients are self-funding.<sup>27</sup> Fertility treatment is expensive; the HFEA estimates that a single fresh cycle of IVF costs patients on average around £5,000, but we have heard from patients that it can cost in the region of £20,000 once all additional costs are taken into account. (Pricing is discussed further in chapter 4).
- 2.17 Patients in most parts of the UK have a number of clinics to choose from. The highest concentration of clinics is in London where there are 25 licensed clinics offering IVF treatment, followed by the Southeast of England where there are 10 licensed clinics offering fertility treatment, whilst the West Midlands and Northwest of England each have 9 licensed clinics offering IVF treatment.<sup>28</sup> There are licensed clinics across all regions of England and in the Devolved Nations.
- 2.18 Clinics are actively marketing their services to prospective patients, for example on websites, in local media, at trade shows and clinic events, and appear to be competing on price, success rates, and the treatments they offer.
- 2.19 As well as patients having a choice between clinics, many clinics also offer a range of add-on tests and treatments which patients can choose to buy on top of their cycle. There is significant choice for patients in relation to add-on treatments and an increasing number of different add-on tests and treatments

<sup>&</sup>lt;sup>22</sup> For example, FutureLife acquired CRGH in August 2022. News story: FutureLife acquires London's largest IVF clinic LICLG

clinic | ICLG

23 For example, Genesis Healthcare LLP (trading as Leeds Fertility) became part of the Care Fertility group in February 2022. News story: Advised CARE Fertility on acquisition of Leeds health clinic | Browne Jacobson

24 HFEA, State of the Fertility Sector 2020/21, November 2021.

<sup>&</sup>lt;sup>25</sup> 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: https://www.hfea.gov.uk/media/1whdur0z/2021-06-16-state-of-the-sector-underlying-data.xlsx

<sup>&</sup>lt;sup>26</sup> Health insurance policies in the UK do not tend to cover fertility treatment.

<sup>&</sup>lt;sup>27</sup> The share of IVF cycles funded by the NHS has declined across most English regions over recent years and in some areas of England clinical commissioning groups do not fund fertility treatment at all. NHS funding is set nationally in the Devolved Nations but a similar decline can be seen with NHS-funded cycles in Wales (39% of cycles NHS-funded in 2019 compared with 42% in 2014) and Northern Ireland (34% of cycles NHS-funded in 2019 compared with 50% in 2014). This contrasts with Scotland where, in 2019, the majority of cycles, 62%, were funded by the NHS. HFEA, Fertility trends 2019: trends and figures, May 2021.

<sup>&</sup>lt;sup>28</sup> HFEA, State of the Fertility Sector 2020/21, November 2021.

- on offer across many clinics at an additional cost.<sup>29</sup> (Add-on treatments are discussed further in chapter 6).
- 2.20 There has also been a proliferation of services related to fertility treatment in recent years, often offered by separate businesses. For example, fertility and lifestyle coaches, alternative therapy providers, 30 as well as businesses offering alternative ways to pay for fertility treatment such as multi-cycle package providers and finance providers. Clinics are also increasingly providing patients with the option of buying multi-cycle packages directly from them, as well as through a third party.

# Scope

- 2.21 This compliance review has focused on fertility clinics that offer self-funded treatment to patients in the UK. As highlighted in paragraph 2.3, we considered the practices of HFEA licensed clinics as well as satellite clinics. We have not looked at other businesses operating in the sector such as sperm and egg banks or multi-cycle package providers. We have also conducted a targeted review of the websites of a small number of overseas fertility clinics that market their services to UK patients.
- 2.22 The review has focused on the practices where we had identified previous concerns:
  - Unclear price information and surprise additional charges (in relation to IVF treatment and egg freezing);
  - Misleading success rate information and claims (in relation to IVF treatment and egg freezing);
  - Provision of misleading information or omission of material information in relation to the benefits and risks of certain add-on treatments.
- 2.23 The review has also assessed the fairness of clinics' contract terms and their complaints handling practices, which were also covered in the Guidance.
- 2.24 Alongside our review, the ASA has also been reviewing compliance with its 2021 Enforcement Notice in relation to the advertising of fertility treatments.<sup>31</sup> Some of the advertising claims for fertility treatments that the ASA has been

<sup>&</sup>lt;sup>29</sup> For example, the HFEA recently added ERA to its treatment add-ons traffic lights and also have a form inviting applications for other treatment add-ons to be added to the traffic light list. Treatment add-ons with limited evidence | HFEA

<sup>&</sup>lt;sup>30</sup> For example, the HFEA's National Patient Survey 2021 found that a third of patients surveyed (33%) had used acupuncture. HFEA, National Patient Survey 2021, April 2022.

<sup>&</sup>lt;sup>31</sup> Fertility-Treatments-Enforcement-Notice-FINALPDF.pdf (asa.org.uk)

considering as part of its review are similar to the issues we have looked at. The CMA and ASA have shared information during our respective reviews.<sup>32</sup> We have also written jointly to the sector calling on them to take steps to ensure compliance with consumer law and the CAP codes in light of the findings from our reviews.

## Who is this report aimed at?

- 2.25 The report is aimed at providers of fertility treatment who treat self-funded patients. The report should also be of interest to patients and patient representative organisations, sector regulators (including the HFEA and CQC), the Department of Health & Social Care (DHSC), other businesses active in the fertility sector, overseas clinics, and to international fertility sector regulators and/ or international consumer protection agencies.
- 2.26 Although our review has focused on clinics' commercial practices and contract terms, some of the issues we have identified are likely to be relevant to other businesses active in the sector. We are therefore recommending that these businesses consider how the issues raised in this report and the underlying consumer law principles apply to them.

## What is the purpose of this report?

- 2.27 When we launched the compliance review, we committed to publishing a summary of our findings. The purpose of this report is therefore to:
  - Summarise the findings from our review;
  - Further raise awareness of consumer law and contribute to improved compliance in the fertility sector;
  - Make recommendations to the sector and to the HFEA in light of the findings from our review; and
  - Set out the steps that we expect to take next.
- 2.28 The report sets out our views on the practices and contract terms we have seen during the review. Our views are not binding on the courts or other enforcers. Whether there has been a breach of consumer protection law by a particular business will depend upon the circumstances of the particular case.

<sup>&</sup>lt;sup>32</sup> In accordance with information sharing gateways under Part 9 of the Enterprise Act 2002 and the MoU between the CMA and ASA dated June 2017

This report is not a substitute for independent legal advice. Ultimately, only a court can decide whether a particular term or practice is unfair.

## 3. The Review

#### Introduction

- 3.1 This chapter summarises the methodology we adopted to assess clinics' compliance with consumer law. The findings from our review of compliance are set out in chapters 4 to 8 below.
- 3.2 As part of the review, we also assessed UK fertility clinics' awareness of the Guidance. The findings of this aspect of our review are summarised in paragraphs 3.5 3.11 of this chapter.

#### What the review involved

- 3.3 We carried out the following activities as part of our review:
  - Commissioned further qualitative patient research (CMA 2022 patient research).<sup>33</sup> The purpose of the research was to deepen our understanding about when and how patients make decisions about where to buy treatment and which treatments to buy. The CMA 2022 patient research built on patient research that we commissioned in 2020 (CMA 2020 patient research).<sup>34</sup> We have published the findings from the 2022 patient research alongside this report.
  - Carried out a review of publicly available information on clinics' websites.
    The website review focused in particular on information relating to price,
    success rates, add-on treatments as well as contract terms and complaint
    handling policies. Clinic websites were selected on a random sampling
    basis and included private and NHS settings offering self-funded fertility
    treatment.
  - Conducted a more detailed review of a further sample of private and NHS clinics offering self-funded treatment. These clinics were selected on the basis of the number of self-funded cycles provided and/ or the types of services offered to self-funding patients, for example add-on treatments and elective egg freezing. In addition to reviewing publicly available information on clinic (and clinic group) websites, we also requested from these clinics details of the standard information provided to patients by means other than clinic websites. Again our reviews focused on price, success rates, treatments add-on, contract terms and complaint handling

<sup>&</sup>lt;sup>33</sup> Consumer research report (2022)

<sup>&</sup>lt;sup>34</sup> Qualitative Research Report (publishing.service.gov.uk)

policies. The clinics that formed part of the detailed reviews together provided 42% of private IVF cycles in the UK in 2018. Some of these clinics are also part of wider groups that have group-wide information and policies and when their wider group is taken into account they together account for 62% of private IVF cycles provided in the UK in 2018.<sup>35</sup>

- compared what services a sample of London clinics include in their package for a single cycle of IVF, along with the price they charge for the package and any key services they exclude from it.
- reviewed the websites of a small number of overseas clinics to identify and review what information they provide to prospective UK patients researching treatment overseas.
- attended the Fertility Show<sup>36</sup> and assessed the information we collected from exhibitors. The majority of exhibitors were clinics based overseas and marketing their services to UK patients.
- monitored media coverage relating to the sector.
- continued to invite patients and patient groups to tell us about patients' experiences of purchasing fertility treatment.<sup>37</sup>
- sought the views of key stakeholders in the sector including professional bodies and patient representatives on the awareness and understanding of the CMA's Guidance and the impact of the Guidance on compliance with consumer law. We summarise the findings of this in paragraphs 3.5 – 3.11 below.
- published a questionnaire on the CMA's webpages inviting views from within the sector as to their awareness and understanding of the Guidance and its impact. The questionnaire was open between 8 March and 6 April 2022<sup>38</sup> and received 19 responses.
- 3.4 It is important to note that we have not assessed all UK clinics and our compliance review is based on a sample of clinics. In addition, due to the

<sup>&</sup>lt;sup>35</sup> There were 43,089 private IVF cycles in total in 2018. HFEA, State of the Fertility Sector 2019/20, underlying data set: https://www.hfea.gov.uk/media/3289/state-of-the-sector-2019-20-underlying-data.xlsx

<sup>&</sup>lt;sup>36</sup> The Fertility Show took place between 7-8 May 2022 at Olympia London. The Fertility Show is an event about fertility run in association with Fertility Network UK. https://www.fertilityshow.co.uk/

<sup>&</sup>lt;sup>37</sup> We have had a call for information from patients about their experiences of self-funded fertility treatment on our webpages

<sup>&</sup>lt;sup>38</sup> The questionnaire was publicised on the CMA's social media platforms, via the HFEA's Clinic Focus newsletter, and by the professional bodies – BFS and ARCS.

sensitive and personal nature of fertility treatment the CMA is not party to what is said to patients in private medical conversations and consultations, so we have not been able to consider this part of the patient journey in our review.

#### What the CMA heard from stakeholders

- 3.5 The professional bodies and patient representative organisations that we spoke to during the compliance review told us that they believed the CMA's Guidance had helped to raise awareness of consumer law obligations in the sector, particularly amongst private clinics. Some anecdotal observations were made by some stakeholders that NHS providers had been focused on the response to the COVID-19 pandemic and therefore clinics providing self-funded treatment based in NHS settings may not have made as much progress in ensuring compliance with consumer law as some private clinics.
- 3.6 In response to the CMA's questionnaire for the sector (referred to at paragraph 3.4 above) we heard that that majority of respondents were aware of the Guidance (16/19 respondents) and most respondents agreed that the CMA's work in the sector has had a positive impact on fertility clinics' overall awareness of their consumer law obligations (11/19 respondents). Examples of positive impact cited included giving clinics confidence that they are acting in accordance with best practice, helping to improve cost transparency, and helping the sector to recognise that self-funded fertility patients are also consumers with rights under consumer law.
- 3.7 However, a small number of respondents (5/19) said that they didn't know if the CMA's work had had a positive impact on overall awareness of consumer law and a few respondents (3/19) thought the CMA's work in the sector had had a negative impact. Though no-one explained why they thought this would be the case. One respondent suggested that some clinics are ignoring the Guidance and another suggested that in their view the Guidance did not reflect clinics' legal obligations as patients' journeys vary on a clinic-by-clinic basis.
- 3.8 The majority of respondents to the questionnaire (13/19) said that there was more the CMA could do to raise fertility clinics' awareness of consumer law obligations. Suggestions included CMA involvement in HFEA clinic inspections to embed compliance with consumer law, targeting measures to raise awareness of consumer law at all clinic staff rather than just staff at senior levels, and publication of case studies and/ or good practice examples. Respondents to the questionnaire did not however specify the areas where they would welcome case studies or good practice examples.

- 3.9 The CMA's questionnaire asked whether any areas of the Guidance could benefit from further clarification. A small number of respondents (4/19) said that there were areas of the Guidance that could benefit from clarification. Comments included that add-ons were still being widely sold and that clinics could benefit from greater clarity on what is considered material information in respect of specific treatments. Add-on treatments are discussed further in chapter 6 below. One respondent commented that the Guidance should recognise that fertility treatment evolves during the patient journey and as such it may not be possible to set out in advance all the ways in which proposed treatment may vary.<sup>39</sup> Price variation is discussed in paragraphs 4.43-4.48 below and variation of contract terms is discussed in paragraphs 7.27-7.31 below.
- 3.10 To further help clinics understand their obligations, throughout chapters 4 - 8below we have sought to give examples of potentially non-compliant practices.
- 3.11 The CMA is responsible for enforcing consumer law but does not conduct regular inspections of clinics. The HFEA is required to inspect licensed clinics every two years to consider whether licensed clinics are operating in line with the HFEA's code of practice. The latest HFEA code of practice, revised in October 2021, states that clinics should have regard to CMA Guidance and clinics should be aware of their obligations under consumer law. 40 As set out in chapter 4, following the findings from the compliance review, we are making a recommendation to the HFEA that reviewing costed treatment plans be made an inspection priority to ensure that clinics provide all patients with the information set out within the HFEA's code, which includes some material information required under consumer law. We are happy to work with the HFEA and the sector on this point. We are also happy to participate in any events or other activities organised by the professional bodies or wider sector organisations to raise awareness of consumer law.

21

<sup>&</sup>lt;sup>39</sup> Point 13(c) of Table 1 of the CMA's Guidance explains that clinics should provide patients with information about reasonably foreseeable changes to treatment and costs at stage 2, the pre-treatment stage, of the patient journey (our emphasis).

40 Paragraphs 4.1, 4.10, 4.12 and 4.13 of the HFEA Code of Practice, 9<sup>th</sup> Edition, revised October 2021.

# 4. Price Information

#### Introduction

- 4.1 A key driver for the CMA's work in the fertility sector were concerns around a lack of price transparency, for example:
  - patients being unable to make meaningful comparisons between clinics' prices because of the way that some clinics present misleadingly low headline prices;
  - some patients not being given clear information about what they would pay before they commit to treatment;
  - some patients facing unexpected additional costs after the treatment plan had been agreed.
- 4.2 The importance of clinics providing patients with clear, accurate and timely information on price formed a key part of the Guidance and it has also been central to this compliance review.
- 4.3 This chapter sets out how and when cost information impacts on patient decision-making, drawing on the CMA's 2020 and 2022 patient research. It gives a brief overview of how consumer law applies in relation to the provision of price information and then summarises the findings of the compliance review. It also sets outs that more consistency across clinics in what is (a) included in the price of a single cycle package of IVF and (b) how additional key costs are presented alongside this cycle package price, would allow patients to compare clinics' prices more effectively. It concludes by setting out recommendations to the sector and the HFEA.

## The importance of price to patients

4.4 In England, Wales and Northern Ireland, over 60% of patients pay for their treatment, 41 with most self-funding patients having no choice but to pay for their fertility treatment because there is no NHS funding in their area, they are not eligible for NHS funding, 42 or they have exhausted what NHS funding was

<sup>&</sup>lt;sup>41</sup> HFEA published information reports that NHS funding has declined in the UK overall over the period 2014 to 2019. The figures are in a decline in England from 40% in 2014 to 32% of cycles in 2019, in Wales, from 42% to 39% and in Northern Ireland, 50% to 34%. Only Scotland saw a rise of NHS-funded cycles from 58% in 2014 to 62% in 2019. HFEA Fertility treatments 2019 trends and figures

<sup>&</sup>lt;sup>42</sup> For example, they or a partner may already have a child, or they may not meet the age or BMI criteria for NHS funding as set by their local Clinical Commissioning Group (CCG).

available to them. Only two participants in our 2022 patient research said that they were eligible for NHS funding but chose to self-fund due to lengthy waiting times for NHS funded treatment.

"I was on the waiting list for the NHS for a very long time, so that's why we decided to go private [self-fund] and now I am 14 weeks pregnant. I only found out that I was at the top of the list when I actually fell pregnant."

- [41, Scotland, Private clinic]<sup>43</sup>

"We were considering doing the treatment through the NHS, but 8 months was just too long to wait for a consultation and to start the process. So then we spoke to a friend that had successful treatment and she recommended another clinic close to us."

- [35, West Midlands, Private clinic]44

# Fertility treatment is expensive

- 4.5 Fertility treatment is expensive, with a single cycle of IVF costing patients on average around £5,000 according to the HFEA, who also say that prices can vary considerably. This price may exclude a number of costs, such as initial investigations and some medication, depending on which treatments and services are included in, or excluded from, the clinics' package price for a cycle. The CMA is aware of single cycles of IVF treatment costing patients in the region of £20,000 once all additional costs are taken into account. However, no information is collected from clinics on what patients in the UK have actually paid for their treatment. So it is not currently known what the average price paid for a cycle of treatment is, or the extent to which this varies between clinics.
- 4.6 For patients looking to preserve their fertility by freezing their eggs and then using their eggs at a later date, the anticipated total cost for a single egg freeze cycle followed by one egg thaw cycle is reported by the HFEA to be between £7,000-£8,000.<sup>46</sup>
- 4.7 For many patients, buying fertility treatment is not a one-off purchase,<sup>47</sup> as most IVF cycles are sadly unsuccessful. Patients can spend many thousands of pounds over the months and years that they undergo treatment. Similarly, patients who elect to freeze their eggs may be advised to purchase multiple

<sup>&</sup>lt;sup>43</sup> CMA 2022 research (section 3.2, page 20)

<sup>&</sup>lt;sup>44</sup> CMA 2022 research (section 3.2, page 20)

<sup>&</sup>lt;sup>45</sup> In vitro fertilisation (IVF) | HFEA

<sup>46</sup> www.hfea.gov.uk/treatments/fertility-preservation/egg-freezing

<sup>&</sup>lt;sup>47</sup> On average a patient has 3 cycles of treatment - https://www.hfea.gov.uk/media/3158/fertility-treatment-2018-trends-and-figures.pdf

cycles of treatment to collect and store a sufficient number of eggs, and they may also require multiple egg thaw cycles to try to achieve a successful outcome.

# Self-funding patients come from a range of different socio-economic backgrounds and there is wide variation in how they fund their treatment

- 4.8 There is a general lack of data on the socio-economic status of self-funding patients, but patient groups have told us that self-funding patients come from a wide range of backgrounds and have varying levels of income. Participants in our 2022 patient research came from different socio-economic groups and there was wide variation in how they funded their treatment. This ranged from using their savings, gifts from parents, loans from siblings, personal loans, credit cards, re-mortgaging their house, inheritance, redundancy pay outs, or often a combination of these.
- 4.9 The 2022 patient research also found that the way in which patients funded their treatment could have an influence on their treatment choices. In particular, patients who took out loans or credit cards, or who had their treatment funded by family members, appeared to be more likely to spend longer considering decisions around the cost of treatment.

# Price is an important factor for many prospective patients when they are choosing between clinics

- 4.10 When developing the Guidance, patient representative groups told the CMA that the cost of treatment is an important factor for many patients when deciding where to have treatment. The HFEA's 2021 National Patient Survey<sup>48</sup> indicates that 39% of respondents who entirely self-funded their treatment identified cost as one of the most important factors when choosing a clinic. This was also a key finding from our 2020 patient research.<sup>49</sup> This research found that price, along with location, success rates and a positive impression of staff, were the key factors that influenced patients' choice of clinic.
- 4.11 This research also found that for a small group of participants, with considerable budget constraints, cost was **the** single most important factor when choosing a clinic. For example:

'We live in Scotland but travel down south because it's a third of the price. It

<sup>48</sup> www.hfea.gov.uk/about-us/publications/research-and-data/national-patient-survey-2021/

<sup>&</sup>lt;sup>49</sup> CMA 2020 Patient Research (section 4.2 page 20)

4.12 Similarly, our 2022 patient research found patients generally carried out a first sift of clinics based on two factors: location and price. Patients typically decided how far they were willing to travel and then selected all the clinics within that distance. They then used the price information on clinic websites to build a sense of which clinics offered treatment that was broadly in line with their budget, as well as which clinics were priced competitively compared to others in their local area.

# Price is most important in patient decision making in the early research stage when they are shortlisting clinics

4.13 An important finding from our 2022 patient research is that price is **most** significant in patients' decision-making at the early stages of the short-listing process.

"We looked at prices, then we could see if we could call someone for more information, and then we'd look at price again. It was a bit like getting insurance quotes. We cross-referenced them all against each other." [36, Midlands, Private clinic] <sup>51</sup>

4.14 Patients in the research also tended to engage with price information again in their initial consultation with their chosen clinic. However, by this stage, the vast majority of patients had already decided where they would buy their treatment from. Generally, the only further decisions made by patients at this stage were about which treatment(s) they would choose.

"We'd made the decision [about which clinic to buy treatment from] before going to the consultation. Me and my partner didn't want to go to a consultation and just mess everyone around, so we just went to the one we knew we were going to go for. The consultation was pretty important to be honest, because obviously you don't know the dangers and stuff, and you don't know fully what you're going to go through [when treatment begins]. They did explain it quite well to be fair, what to expect, what we had to do and how long it'd take and stuff like that. And in terms of actually deciding what treatment we wanted to buy, we decided that about 2 weeks after the consultation." [26, West Midlands, Private clinic]<sup>52</sup>

<sup>&</sup>lt;sup>50</sup> CMA 2020 research (paragraph 4.2.3, page 21)

<sup>&</sup>lt;sup>51</sup> CMA 2022 research (section 5.3, page 50)

<sup>&</sup>lt;sup>52</sup> CMA 2022 research (section 5.3, page 52)

4.15 These findings underline the importance of clinics providing transparent price information upfront, particularly on their websites, given this is where patients look for information when they are shortlisting clinics and comparing them on price.

Some patients purchasing subsequent rounds of treatment focused less on price information because they had experienced the cost of previous cycles unexpectedly changing once treatment had begun

4.16 Our 2022 patient research also found that patients purchasing a subsequent round of treatment were less likely to base their final decisions about where to buy treatment, or which treatments to buy, around pricing. These patients were likely to place less importance on price information because they had experienced the cost of their previous treatment changing (for some, substantially) once treatment had begun due to the unexpected cost of additional tests, scans and medication. Due to the sums of money that patients invested in their treatment and their incredibly strong desire to have a child, their main priority was to ensure that the money they spent on treatment gave them the greatest chances of success. Providing a clinic's pricing was perceived to be broadly in line with that of other local competitors and within their broad budget range, these patients were more likely to choose a clinic based on a sense of how successful their treatment there would be.<sup>53</sup>

'After our first round and realising just how much the prices vary as you go through the process, we definitely focused less on scrutinising the costs between different clinics. There was just no point!' [46, North, Private clinic]<sup>54</sup>

4.17 The CMA heard anecdotally through its engagement with stakeholders that some UK patients go overseas to have fertility treatment because they think it will be cheaper.<sup>55</sup> A few participants in the CMA's 2020 patient research who had 5 or more cycles of treatment explained that they had switched to clinics abroad to manage the costs over a long period of time. For example:

'The main driver was cost initially, plus reputation. It's significantly cheaper [abroad]. In the UK, an IVF cycle costs between £6-7k. In a

<sup>&</sup>lt;sup>53</sup> CMA 2022 research (section 5.3, page 53)

<sup>&</sup>lt;sup>54</sup> CMA 2022 research (section 3.2.3, page 27)

<sup>&</sup>lt;sup>55</sup> EHSRE has suggested that one of the reasons why patients travel outside their country of origin for fertility treatment is for less expensive treatment. EHSRE, Cross border reproductive care factsheet, January 2017.

Czech clinic it would be max £2k, including air fares and accommodation'. [Mixed sex, 38-42, Private, South East]<sup>56</sup>

# Price is an important factor for some patients when they are choosing between treatment options

4.18 Our 2020 patient research highlighted that some patients also take price into account when considering and deciding on their treatment options at their chosen clinic. For example:

'Nothing extra was included. As our parents paid for this, we were conscious of not adding to the price'. [Mixed sex, 38-42, Private, South East]<sup>57</sup>

'We discussed the cost as well and the IVF was as much as we could stretch to. They did mention other things in passing, but there wasn't a lengthy discussion because there wasn't the money there to have anything else.' [Mixed sex, 38-42, Private, Northern Ireland]<sup>58</sup>

4.19 Our 2022 patient research also found that for a minority of patients who were particularly concerned with being able to find further funding for treatment following the purchase of their next round, multi-cycle packages presented an alternative route to managing both chances of success and costs. They wanted the reassurance of knowing that they would pay a set price for a certain number of cycles.

'We decided to move onto private clinics because of the lack of financial packages at the NHS. If it didn't work, you would lose all your money but at other clinics there was the option for other forms of payments. For example, pay for 3 and if it didn't work you'd get your money back.' [40, North, Private clinic]<sup>59</sup>

'These packages aren't offered everywhere. Once I'd learnt that these packages existed, I didn't want a single round of IVF. If I had to start my search again, I would have gone for who offers packages.

<sup>&</sup>lt;sup>56</sup> CMA 2020 research (paragraph 4.2.6, page 22)

<sup>&</sup>lt;sup>57</sup> CMA 2020 research (paragraph 4.2.4, page 21)

<sup>&</sup>lt;sup>58</sup> CMA 2020 research (paragraph 4.3.34, page 45)

<sup>&</sup>lt;sup>59</sup> CMA 2022 research (section 5.3, page 51)

Packages became very important to me in terms of justifying that value.' [41, North, Private clinic]<sup>60</sup>

# While price is an important factor for many patients, some feel reluctant to raise questions relating to price with their clinic during consultations

4.20 The CMA's discussions with patient groups highlighted that while price is an important factor for many patients, some patients feel reluctant to ask questions or raise issues relating to price with their clinic during consultations and as they go through treatment. The CMA's 2020 patient research also found that some participants found it was difficult to raise the topic of price within the context of fertility treatment – when respondents felt that they should be demonstrating how much they wanted a baby:

'You're so hopeful for success and you want to keep positive all the time, so any kind of conversation about it being overly expensive or out of reach is not a conversation you want to have.' [Mixed sex, 40+ years old, Private, East Midlands]<sup>61</sup>

'The clinical director said that there is a medical trial going on with this drug and that she highly recommended it. So of course we said yes. I remember walking out and saying to [partner], 'I've got no idea how much that costs'. But when you are in your gown, you are about to go in, you don't say 'how much is that going to cost?' [Mixed sex, Under 35, Private, West Midlands]<sup>62</sup>

4.21 The views expressed above highlight why it is so very important that clinics provide clear and accurate upfront price information to prospective patients before they book an initial consultation, for example on clinic websites and in brochures, and following a consultation, before they commit to treatment.

<sup>&</sup>lt;sup>60</sup> CMA 2022 research (section 5.3, page 51)

<sup>&</sup>lt;sup>61</sup> CMA 2020 research (paragraph 4.2.5, page 22)

<sup>62</sup> CMA 2020 research (paragraph 4.2.5, page 21)

## How consumer law applies to pricing information

- 4.22 Consumer law requires<sup>63</sup> that existing and prospective patients<sup>64</sup> are provided with material information at the time that they need it, and in a format that is clear and easy to understand. This includes information about the anticipated price of treatment. Where the presentation or omission of material information gives rise to a misleading impression that is likely to cause consumers to take a different transactional decision such as their choice of clinic from which to buy treatment or which treatments to buy the CPRs are likely to have been breached.
- 4.23 What is considered "material" price information will vary as the patient journey progresses. <sup>65</sup> For example, at the initial research stage, before the patient has attended a consultation, price information provided to patients via clinic websites or other means, will need to include a reliable indication of how much they can expect to pay throughout the patient journey. <sup>66</sup>
- 4.24 Once the results of the pre-treatment scans and tests are known and a treatment plan has been provisionally agreed, patients should be provided with tailored information explaining the treatment and services that the clinic will provide. This should also set out the anticipated total price and provide information about any additional costs that may need to be incurred depending on how treatment progresses.<sup>67</sup> Where elements of the treatment may be uncertain or the price of certain elements cannot reasonably be determined in advance, clinics should explain how those elements of the price will be determined and provide a reasonable estimate of the likely additional cost. This information should be provided before the patient commits to proceeding with treatment.
- 4.25 The different categories of prices, which are likely to be relevant during the patient journey can be broadly summarised as follows:
  - **Essential items**, the price of which are **known** this is likely to include:

<sup>&</sup>lt;sup>63</sup> See chapter 3 of the CMA's Guidance.

<sup>&</sup>lt;sup>64</sup> This includes, where relevant, partners too.

 $<sup>^{65}</sup>$  See paragraphs 3.21 - 3.31, Table 1, page 31 paragraphs 3.54-3.57 and Table 2, page 54 of the CMA's Guidance

<sup>&</sup>lt;sup>66</sup> This is likely to include pre-treatment costs, costs incurred during a cycle of treatment and any future costs directly associated with the treatment that will need to be factored in at a later date.

 $<sup>^{67}</sup>$  See paragraphs 3.32 – 3.38, Table 1, page 31, paragraphs 3.54-3.57 and Table 2, page 54 of the CMA's Guidance

- (a) **Pre-treatment** for example the consultation(s) and the diagnostic investigations that the majority of patients will require, such as the baseline scan, AMH blood test and screening tests.
- (b) **Treatment** nurse or consultant appointments, monitoring scans, egg collection procedure under sedation, embryo transfer and the fee that the HFEA charge clinics.<sup>68</sup> Monitoring blood tests also fall into this category at many clinics as they are all included in the cycle price.
- Essential items that all patients will incur but where it is not possible to
  provide an exact price most notably this usually includes the price of
  medication, the amount of which will be based on the drug protocol agreed
  once the results of the initial investigations are known and which may also
  change during treatment.
- Additional items that may be required or recommended depending on how treatment progresses. This includes the price of items such as blastocyst culture if it is the clinic's intention to progress to a day 5 or 6 embryo transfer, pregnancy-related elements of treatment (e.g. scans, blood test and medication), and the price for freezing and storing any surplus embryos, if the patient intends to do this. It may also include the price of items such as ICSI or additional medication if the patient does not respond to treatment as anticipated. There may also be other future charges directly associated with the treatment that will need to be factored in at a later date, such as the ongoing storage of frozen eggs or an egg thaw cycle.

# **Findings from the Compliance Review**

#### **Compliance Review Activities**

- 4.26 Between December 2021 and June 2022, we reviewed a sample of clinics to assess how the required pricing information is made available to patients.
- 4.27 Our review initially involved assessing the pricing information available on clinics' websites. In February 2022, as part of a more detailed review, we asked a further sample of private and NHS clinics to provide us with any additional standard price information they give to prospective patients before they commit to treatment. This included information provided to patients when first contacting the clinic, before attending a consultation and once a treatment

<sup>&</sup>lt;sup>68</sup> The HFEA charges a fee to the clinic when an embryo transfer or donor insemination is carried out. Most clinics choose to pass this fee onto the patient.

- plan has been agreed. These clinics together provide a significant proportion of private IVF cycles in the UK for example in 2018 42% of private cycles.<sup>69</sup>
- 4.28 Overall, we found a mixed picture in terms of compliance with consumer law. For a small minority of all the clinics we reviewed we found no compliance concerns in relation to their price information. Whilst conducting the review we noted that several clinics, and especially those clinics that we had requested further information from, were making changes to the price information available on their websites following the CMA and ASA's work in the sector. Positively, the changes typically resulted in improved compliance with consumer law (see paragraph 4.66 below).
- 4.29 However, we found compliance issues with the majority of the clinics we reviewed, albeit that in some cases these were relatively minor.
- 4.30 Following our more detailed reviews, we wrote to certain clinics setting out the specific compliance issues we had identified with them. We told these clinics that we expected them to review their practices and terms and make appropriate changes to ensure their compliance with consumer law. 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. Examples of these changes are discussed at paragraph 4.69.

# Summary of findings:

- 4.31 The main findings from our review of price information were:
  - The transparency of price information varies between clinics.
  - We continued to identify concerns with how some clinics provide price information to patients, both at the initial research stage (when patients are comparing clinics) and prior to agreeing to treatment with their chosen clinic.
  - There have been improvements in how some clinics provide price information since we published our Guidance and the ASA published its Enforcement Notice.

<sup>&</sup>lt;sup>69</sup> Some of these clinics are also part of wider groups that have group-wide information and policies and when their wider group is taken into account they account for 62% of private IVF cycles provided in the UK in 2018.

- There have been further improvements following the CMA's and ASA's direct engagement with a sample of clinics
- There is significant variation between clinics in what they include in their headline package price for a single cycle of IVF. This variation is likely to make it difficult for patients to compare clinics' prices at the key shortlisting stage.

#### **Concerns**

- 4.32 Our review identified concerns with some clinics regarding the transparency of price information made generally available to prospective patients at the initial research stage when they are comparing clinics, and also the personalised price information given to a patient prior to them committing to treatment with their chosen clinic. This is discussed in more detail below.
- 4.33 Whilst our review focused on specific treatment options (a single cycle of IVF and egg freezing) the issues highlighted below are likely to generally apply to other available treatment options such as donor treatments and surrogacy.

#### Price transparency when patients are comparing clinics

- 4.34 As highlighted at paragraphs 4.13 4.15 above, price is an important factor for many patients at the early research stage when comparing clinics and choosing which clinic(s) to book a consultation with.
- 4.35 We found that some clinic websites failed to provide patients with the material information needed to understand the costs associated with each stage of treatment. Some clinics also advertised a low headline price for a cycle of treatment, which excluded known essential costs that would have to be incurred before treatment could start and / or if treatment progressed as intended.
- 4.36 We provide examples of the specific concerns we identified during our review below.

#### Transparency of pre-treatment costs

4.37 Before a clinic can recommend a treatment plan, patients (and in some circumstances their partner) will typically need to attend at least one consultation and undertake some diagnostic investigations. The patient journey will vary depending on the clinic and the patient's individual circumstances. For example, the clinic may require patients to attend (and pay for) more than one pre-treatment consultation, and the patient's medical

- history and the results of their initial investigations may mean that further diagnostic investigations are recommended.
- 4.38 However, for an initial cycle of treatment, certain investigations and tests are likely to be needed for the vast majority of patients before treatment can commence, such as a baseline scan, an AMH blood test and screening tests. There are some exceptions to this. For example, if the patient has completed some of these tests very recently, at another clinic or via their GP, they may not need to be repeated. Furthermore, some clinics factor the cost of the screening tests into the treatment cycle price, in which case an additional charge would not be applied.
- 4.39 We found that at a couple of clinics, where it is routine for patients to have to pay for more than one pre-treatment consultation, the clinics in question failed to explain this on their website.
- 4.40 We also observed a lack of clarity on several clinics' websites regarding which diagnostic tests and scans were necessary for all patients and would result in an additional charge.
- 4.41 The degree to which material information was provided to patients varied by clinics. Where we identified concerns, these can be broadly categorised as follows:
  - Quite often some of the relevant pricing information was not available on the clinic's website at all.
  - In several instances the relevant pricing information was provided across different pages of the clinic's website with inadequate signposting, requiring patients to actively search for the information.
  - It was common practice for clinics' websites to include a long list of prices
    that did not indicate which treatments and services were essential for all
    patients and which costs might be incurred depending on the results of the
    initial investigations.

## Advertising a low headline price for a cycle of treatment

4.42 Our review identified several clinics advertising a low headline package price for a cycle of treatment, which excluded essential costs that would have to be incurred. Examples of excluded essential costs included those associated with monitoring blood tests, additional scans that all patients must pay for, and the HFEA fee (where clinics choose to pass this fee onto the patient). In a few cases, clinic websites carried specific claims that the cycle price included all

costs that would be incurred during the treatment cycle, when in fact several necessary costs were excluded.

#### Medication costs

- 4.43 It is typical for the cost of medication to be excluded from the cycle package price, as the cost can vary significantly depending on the patient's specific drug protocol. However, clinics should nevertheless provide a reliable indication of the additional cost associated with medication, for example by providing a realistic price range.<sup>70</sup>
- 4.44 Whilst most clinic websites did include a prominent explanation that medication costs were excluded and provided a price range for medication, several clinics <sup>71</sup> gave no indication of the medication costs anywhere on their website, or the information was available but not adequately signposted from the webpage displaying the price list. We also observed a couple of instances of contradictory prices for medication being displayed in different places on the same clinic's website.
- 4.45 This was a particular concern as we found that the advertised cost of medication (where available) varied significantly between clinics, reinforcing the importance of providing this price information so that patients can make an informed choice about where to have treatment. For example, in respect of those clinics that provided information on medication costs, the lowest price range for a single cycle of IVF was stated to be £250-£900, whereas the highest range was £1,500-£4,250.

Costs which 'may' become necessary or are routinely recommended by the clinic

4.46 Some clinic websites displayed unclear or confusing information regarding costs that were excluded from the headline cycle package price, but which might be incurred if treatment progressed as planned. This included the price for items such as a blastocyst transfer, embryo storage, pregnancy scans and pregnancy medication. Price information was either not included anywhere on the price list, or it was difficult to locate within a long list of prices with no explanation of the circumstances in which patients might incur these costs. For example, at one clinic items such as blastocyst transfer, surplus embryo freezing and/or storage and the fee that the HFEA charge clinics, were

<sup>&</sup>lt;sup>70</sup> See paragraph 3.25(b) of the CMA's Guidance.

<sup>71</sup> All of the clinics that the CMA contacted have since amended their websites (or have agreed to amend their websites) to ensure this information is displayed clearly and prominently.

- advertised on one page of the clinic website as being included in the package cycle price, but said to be excluded on other pages of the same website.
- 4.47 Our review also identified several examples of clinics' websites failing to provide material information about the total costs associated with egg freezing. These included:
  - Clinic websites that provided the price of an egg freezing cycle but failed to explain that patients may need to purchase more than one cycle to collect and store the number of eggs recommended by the clinic. Only a small number of clinic websites included information on the recommended number of eggs to be collected and stored, which ranged between 10 and 30 depending on the age of the patient. We found that the package price advertised for a single egg freeze cycle ranged from £2,450-£4,760, not including the cost of medication, (although most clinics offered a multi-cycle egg freezing package which provided price savings compared to purchasing the same number of cycles individually).
  - A few clinics failed to provide information about the future price of storing the frozen eggs. Our analysis found that the annual price of storage ranged between £165-£420, with a few clinics offering longer term plans at a discounted rate. For patients that are looking to preserve their fertility for a number of years,<sup>72</sup> the ongoing cost of storage can therefore be considerable.
  - Several clinics failed to provide adequate information about the need for, and cost of, an egg thaw cycle should the patient use their frozen eggs in the future. For those clinics that did advertise the cost of an egg thaw cycle, the advertised package price ranged between £2,000 - £4,835, not including the cost of medication, which we would expect to be in line with the cost of medication for a frozen embryo transfer.
- 4.48 Given the significant amounts involved in the above examples, and taking into account the variation in the prices charged by clinics for these treatments and services, the failure to provide a clear and prominent indication of these prices upfront is likely to result in some patients being surprised by the additional costs that need to be factored in. The omission of this material information is also likely to impair prospective patients' ability to make an informed decision

<sup>&</sup>lt;sup>72</sup> As from 1 July 2022 patients can store their eggs for any period up to a maximum of 55 years from the date that the eggs are first placed in storage.

when comparing the cost of treatment at different clinics or when deciding whether to pay for egg freezing treatment at all.

#### Misleading price comparisons

- 4.49 During the review we found that a couple of clinic websites advertised price savings by comparing their cycle prices against their competitors' prices. This in itself is not a breach of consumer law, but particular care should be taken when advertising price comparisons. Due to the significant variation in the services that are included in a package price for a single cycle of IVF (see paragraphs 4.72-4.77 below), ensuring that any comparison remains accurate and that any claimed savings are genuine is likely to be very difficult to achieve in practice.
- 4.50 By way of example, we observed instances where the claimed savings were likely to be misleading to patients as comparisons were not being made on a like-for-like basis, or the cycle price quoted for the competing clinic was incorrect. This included where the clinic's cycle price was advertised as "saving £x" when compared against the higher price charged by competing clinics. However, our further analysis identified that the higher price charged by some of the other clinics included additional elements of treatment, such as the freezing and storing of surplus embryos, which were excluded from the original clinic's cycle price.
- 4.51 Price comparisons that are presented as offering a saving must represent a genuine saving for consumers to comply with consumer law.

#### Clinics based overseas

- 4.52 Our targeted review of the websites of a small number of overseas fertility clinics that market their services to UK patients found that approximately half of the clinics reviewed failed to include any pricing information on their websites. Instead, patients were advised to contact the clinic directly to obtain the relevant price information.
- 4.53 Where price information was given for a cycle of IVF, we saw examples of clinics providing a headline price without explaining which treatments and services were included or excluded from it.
- 4.54 In other cases, it was explained which treatments and services were excluded, such as monitoring blood tests, medication and scans, but no information was provided about the price of these elements. One clinic suggested that medication would need to be purchased in the patient's home country and gave an estimated cost.

- 4.55 Most of the overseas clinics we looked at advertised surrogacy and IVF with donor eggs and/ or sperm. Few gave information about the price of these treatments or where it was provided it was often no more than a headline price.
- 4.56 We also saw examples of unsubstantiated claims by clinics to be the cheapest, to provide the 'most affordable' treatment, and to offer low prices when compared to the UK.

#### Price transparency when agreeing a price for treatment

- 4.57 Two other issues around price transparency that led to our work in this sector were (1) patients not being given clear information before they commit to treatment about the price of their treatment, and (2) patients being faced with unexpected additional costs after the treatment plan had been agreed.
- 4.58 Several stakeholders raised these problems with the CMA as we developed our Guidance, and these issues were also highlighted in our 2020 patient research. The HFEA's most recent National Patient Survey<sup>73</sup> also highlighted similar concerns: amongst patients surveyed in 2021, approximately one in five (18%) of those who entirely self-funded their treatment said that cost information was not clearly communicated to them before they agreed to treatment.
- 4.59 Our 2020 patient research, and patient experiences reported to the CMA via patient representative groups, indicated that unexpected additional costs most often arose after patients' treatment plans had been agreed because of a lack of prior information about the anticipated cost of medication (including the possible need for, and cost of, additional medication after treatment has begun, including after a positive pregnancy test). Similarly, the cost of essential blood tests, and the need for, and cost of, additional monitoring blood tests, scans and consultations during the course of treatment at some clinics came as a surprise to some patients.
- 4.60 Other 'surprise' costs related to treatments and services which became necessary or were recommended by the clinic as treatment progressed, such as a dummy embryo transfer, pregnancy scans, and surplus embryo freezing

<sup>73</sup> https://www.hfea.gov.uk/about-us/publications/research-and-data/national-patient-survey-2021/

- and storage. It also included additional treatments which were recommended by the clinic during treatment such as time-lapse imaging and embryo-glue.
- 4.61 A small minority of patients in our 2020 research said that their clinics had not provided them with a price for treatment *at all* before they agreed to have treatment.

#### Costed Treatment Plans

- 4.62 The HFEA's code of practice<sup>74</sup> clearly sets out that before treatment is offered, clinics should provide a personalised costed treatment plan, setting out the main elements of the proposed treatment, including investigations, tests and treatment add-ons, the price of the treatment and any possible changes to the plan, including price implications. The clinic should give patients the opportunity to discuss the plan before treatment begins. The above requirements are also relevant under consumer law.
- 4.63 As part of our compliance review, we requested copies of standard price information shared with patients, including template costed treatment plans, from a sample of clinics. The purpose of this exercise was to assess how clinics make the required price information available to patients before they commit to treatment.
- 4.64 This exercise had some limitations, in that we did not collect completed / unredacted costed treatment plans and we were therefore not able to observe how this information was presented to patients in full. However, the information we reviewed suggests that a **personalised** costed treatment plan was not provided by some clinics before the patient commits to treatment. Instead, some clinics only provided generic pricing information that does not appear to reflect the patient's individual circumstances. For example, we saw sample costed treatment plans which failed to set out the specific treatments and services that were to be provided by the clinic as part of a cycle of treatment. Furthermore, some costs, such as the price of medication, continued to be displayed as a broad price range at this stage, for example £1,500-£2,500, rather than an accurate price / price estimate based on the agreed drug protocol.
- 4.65 Positively we have also seen examples of costed treatment plans that we do consider comply with consumer law and the HFEA's code.

<sup>&</sup>lt;sup>74</sup> https://portal.hfea.gov.uk/media/ihkjnfqq/2022-07-01-code-of-practice-2021.pdf

#### Improvements in how clinics provide pricing information

- 4.66 Following the publication of the CMA's Guidance and the ASA's Enforcement Notice, we have seen a number of positive changes in clinics' practices. We could also see that those clinics that we reviewed in detail were continuing to make changes during the course of our reviews. In particular, we have seen improvements in how some clinics 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. These practices help provide patients with a more realistic indication of the likely cost of their fertility treatment, reducing the likelihood of them being surprised by additional costs, and allowing them to compare costs across different clinics more effectively at the shortlisting stage. Examples of the positive changes include:
  - Clinics being more transparent about the need for, and cost of, pretreatment tests, investigations and consultations and that these costs are in addition to the advertised package price for a cycle of treatment.
  - Clinics making patients aware of the need for, and cost of, essential elements of treatment which are excluded from the treatment package price. This includes elements of treatment such as medication and blood tests, both of which can significantly increase the price of a treatment cycle. We found in our review that clinics' advertised price for medication for a single cycle of IVF can vary significantly, ranging from between £250 to £4,250, and in-cycle monitoring blood tests, which some clinics do not include in their package price, were advertised at up to £1,500.
  - Clinics including more realistic estimated 'total prices', which factor in the
    cost of treatments and services that are excluded from the treatment cycle
    price, but which are likely to be needed or recommended by the clinic if
    treatment progresses as intended. This includes elements such as
    blastocyst culture, time-lapse imaging and freezing and storing surplus
    embryos. In some instances, the price of pre-treatment consultations and
    investigations were also factored in.
  - Clinics removing contradictory price information from different pages of their websites, which was likely to confuse patients about which costs were included in the cycle package price.
  - Clinics re-designing pricing webpages to provide patients with key pricing information in easier-to-understand formats. This includes the introduction of dedicated webpages summarising the key stages of the treatment

journey and the relevant costs at each stage, and the use of practical case studies which reflect various example patient journeys.

Clinics have made positive changes following our letters outlining compliance concerns

- 4.67 As explained at paragraph 4.30 above, we wrote to some of the sample clinics we reviewed in detail to highlight specific concerns we had identified with their price information.
- 4.68 All the clinics we contacted have subsequently made changes to address compliance concerns we highlighted to them. We welcome the generally constructive approach adopted by clinics. We are continuing to engage with some of the clinics to resolve a small number of outstanding issues.
- 4.69 Examples of the types of changes include:
  - Clinics providing more accurate, personalised pricing information following the initial consultation. For example, by providing patients with a costed treatment plan which includes detailed medication costs based on the outcome of the initial tests and investigations, rather than a generic price range.
  - Clinics displaying clearer pricing information about the **future** costs associated with treatment on the clinic websites and in the standard information provided to patients via other means. For example, when advertising egg freezing, also providing clear information about the anticipated cost of using their frozen eggs in the future.
  - Clinics amending the format in which pricing information is provided to
    patients to ensure they are provided with consistent information regardless
    of how they interact with the clinics.
  - The removal of potentially misleading price comparison claims.
  - The removal of "all-inclusive" price claims which stated or falsely implied that the cycle price was the total price to be paid by patients.

#### Recommendation

4.70 We strongly recommend that clinics review the price information they provide to patients in the light of the compliance concerns identified in this chapter and take any corrective action necessary as a matter of priority. Clinics should not assume because we have not written to them directly, that their practices

- are compliant with consumer law. Failure to comply with consumer law could result in the CMA, or others, taking enforcement action.<sup>75</sup>
- 4.71 We also recommend that the HFEA makes reviewing costed treatment plans an inspection priority, to ensure that clinics provide all patients with a costed treatment plan and that they provide all the information set out in the HFEA's code, which includes some of the material information required under consumer law. We would be happy to work with the HFEA and the sector on this point.

# Variation between clinics as to what they include in a package price for a single cycle of IVF

- 4.72 As part of the review we recorded the headline package price charged by a sample of clinics for a cycle of IVF treatment, along with the treatments and services included in the cycle price. We also recorded the itemised prices of any elements of treatment excluded from the package price, but which are routinely needed or recommended by clinics if treatment progresses as intended.
- 4.73 Our analysis has revealed significant differences between what clinics include in their headline package price for a single cycle of IVF. The analysis also illustrates that for some clinics there is large disparity between their headline price and the total price to patients (excluding medication) once the price of other excluded elements of treatment are factored in. Ultimately a significant proportion of patients will need to have and pay for these excluded elements of treatment. Indeed, almost all patients will need to pay for some of them.
- 4.74 Table 1 is based on a sample of London clinics<sup>76</sup> and reflects the price information available on the clinic websites or where we obtained additional price information directly from the clinic.<sup>77</sup> Where no pricing information was available for an excluded element of treatment or service for a particular clinic, we used an average price based on the itemised prices charged by the other London clinics that featured in the review.<sup>78</sup>

<sup>&</sup>lt;sup>75</sup> CMA Guidance - paragraph 1.26

<sup>&</sup>lt;sup>76</sup> We know from our consumer research that clinic location, along with price and success rates, is an important factor for patients when choosing a clinic. We therefore compared clinics based in the same region to try and best replicate the start of a patient journey. London was selected as it incorporated a wide range of clinics offering self-funded treatment and a large number of self-funded IVF cycles are carried out in London: 17,019 in 2019 - HFEA Fertility treatments 2019 trends and figures

<sup>&</sup>lt;sup>77</sup> Clinic websites were reviewed between 6/12/21 and 21/12/21.

<sup>&</sup>lt;sup>78</sup> Average price used for time-lapse imaging - £679.

Table 1 - A sample of London clinics and what they charge for, and include in, their package price for a single IVF cycle, along with the price of key services not included in the package price. (On top of this patients will also need to pay for medication. The price of medication varies between clinics and also between patients, according to the individual patients' drug protocol).<sup>79</sup>

|   | Clinic A | Clinic B | Clinic C | Clinic D | Clinic E | Clinic F | Clinic G | Clinic H | Clinic I | Clinic J | Clinic K | Clinic L |
|---|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|
| Advertised package cycle price  | £3300    | £3500    | £4800    | £3750    | £3595    | £4110    | £5825    | £3300    | £3400    | £3850    | £4750    | £3500    |
| Monitoring blood tests  | ~        | ~        | ~        | ~        | ×        | ×        | ~        | ×        | ×        | ×        | ~        | ~        |
| In treatment ultrasound scans   | ~        | ~        | ~        | ~        | ~        | ~        | ~        | ~        | ~        | ~        | ~        | ~        |
| Egg collection  | <b>~</b> |
| Sedation (egg collection)   | ~        | ×        | <b>~</b> | ~        | ×        | <b>~</b> | ~        | <b>~</b> | ~        | <b>~</b> | ×        | ~        |
| Fresh embryo<br>transfer  | ~        | ~        | ~        | ~        | ~        | ~        | ~        | <b>~</b> | ~        | <b>~</b> | <b>~</b> | ~        |
| Blastocyst / extended culture   | ~        | ~        | ~        | ×        | ~        | ×        | ~        | ×        | ×        | ×        | ~        | ~        |
| Time lapse imaging  | ×        | <b>~</b> | <b>~</b> | ×        | ×        | ×        | <b>~</b> | ×        | ×        | ×        | <b>~</b> | <b>~</b> |
| Embryo freezing (plus first year storage)                               | ×        | ×        | ×        | ×        | ×        | ×        | <b>~</b> | ×        | ×        | ×        | ×        | ×        |
| HFEA Fee  | <b>~</b> | ×        | <b>~</b> | ×        | ×        | ×        | <b>~</b> | ×        | ×        | <b>~</b> | ×        | <b>~</b> |
| Pregnancy<br>ultrasound scan or<br>follow up<br>consultation            | ~        | ~        | ~        | ~        | <b>~</b> | ~        | <b>~</b> | <b>~</b> | ×        | ×        | <b>~</b> | ~        |
| Treatment price if all of the above treatments / services were provided | £4779    | £4430    | £5500    | £6135    | £5195    | £7085    | £5825    | £6139    | £6250    | £6777    | £5850    | £4200    |
| Increase from advertised cycle price                                    | £1479    | £930     | £700     | £2385    | £1600    | £2975    | £0       | £2839    | £2850    | £2927    | £1100    | £700     |

 $<sup>^{79}</sup>$  The price of medication for this sample of clinics was typically displayed as a price range with the lowest price range starting at £600 and the highest price range ending at £3000. For a small number of these clinics the cost of medication was obtained after the review period of 6/12/21 - 21/12/21 as the information was not available via the clinic websites at that time.

- 4.75 The CMA's review found that both the headline package price for a single cycle of IVF and the price that patients would have to pay if each of the treatments and services listed in Table 1 were included, varied substantially between the clinics in the sample. The difference between the two figures for a single cycle of IVF at the same clinic varied between £0 and £2975, with the price for all the services listed in the table ranging between clinics from £4,200 to £7,085 excluding medication.
- 4.76 We found that all clinics included in-treatment monitoring scans, the egg collection procedure and embryo transfer in the headline package price for a cycle of IVF. Most, but not all clinics, also included either a pregnancy ultrasound scan in the event of a positive pregnancy test or a follow-up consultation if the pregnancy test was negative, and sedation for the egg collection procedure.
- 4.77 Blastocyst culture, time-lapse imaging and monitoring blood tests were included less frequently and only one clinic included surplus embryo freezing in their cycle package price. These treatments and services cost several hundred pounds each. The HFEA fee of £80<sup>80</sup> was also regularly excluded.
- 4.78 As a result, where several treatments and services are not included there is a significant difference between the headline package cycle price and the final price that patients may well end up paying for their treatment. This may result in some cycle packages appearing more competitive in price than they actually are when compared against more comprehensive options at other clinics.
- 4.79 For example, Clinic H may offer one of the lowest headline cycle prices at £3,300, but this excludes a number of elements such as monitoring blood tests and a blastocyst transfer, which, when added to the total, results in treatment at Clinic H costing significantly more than a number of alternative clinics. In contrast, Clinic G appears to be the most expensive option based on the initial treatment cycle price. However, as this clinic includes all of the listed elements of treatment in the cycle package price, the 'total' price does not increase and patients may pay less at this clinic than several other listed clinics, including Clinic H.
- 4.80 Consumer law requires that clinics are clear about what is included and excluded from the headline price (see paragraphs 4.22-4.24). However, it

43

 $<sup>^{80}</sup>$  The HFEA charge fertility clinics a fee for each cycle of IVF and IUI they perform. The fee has recently increased to £85.

- does not specify what has to be included, as long as the presentation is not misleading,<sup>81</sup> and it does not specify what clinics can charge.
- 4.81 We are concerned that the variation we have seen is likely to make it difficult for prospective patients' to easily and meaningfully compare clinics' headline prices. We would therefore like to work with the sector to explore the feasibility of developing a standard approach for what is included in a headline package price for a single cycle of IVF, along with a consistent approach for presenting the price of additional key aspects of treatment that are not included in that cycle price. We recognise that there could be challenges with developing such an approach.

#### Recommendation

- 4.82 The CMA understands that each patient journey is likely to be different and that clinics take different approaches to providing treatment. However, it is our view that more consistency in a) what is included in and excluded from the headline package price for a single cycle of IVF and b) how the prices of additional key aspects of treatment are presented alongside this cycle price, would allow patients to compare clinic prices more effectively. It would also help provide patients with a more realistic indication of the total price for treatment at different clinics.
- 4.83 We plan to hold roundtable discussions with clinics and other key stakeholders in autumn 2022 to explore the feasibility of developing a standard approach for what is included in the headline package price for a single cycle of IVF as well as a consistent approach to providing price information for any key aspects of treatment not included in the package price. To be clear this is about the presentation of price information, and not any price regulation. We are not trying to standardise the amount that clinics can charge for a single cycle of IVF treatment. The CMA plays no role in determining the prices charged by traders for goods or services, and does not act as a price regulator.

<sup>&</sup>lt;sup>81</sup> As stated in our guidance, the presentation of the cycle of treatment must not be misleading, and it should include all material information. In particular we are of the view that the headline package price for a cycle of treatment should include all compulsory charges where the amount a patient pays is known upfront.

### 5. Success Rate Information

#### Introduction

5.1 This chapter begins by highlighting the importance of success rate information in decision-making for many patients, drawing on our 2020 and 2022 patient research. It gives a brief overview of how consumer law applies in relation to the provision of success rate information, before summarising the findings of our compliance review.

#### Why success rates are important

# Success rates are a key factor for many prospective patients when choosing between clinics

5.2 Research has highlighted the important role that success rates can play when prospective patients are choosing clinics. For example, our 2020 patient research found that clinic success rates were one of four key factors that had influenced most participants' choice of clinic.

'If I was going to do it one more time, this would be the last ever time. I'm 39 - it's not going to work much longer. I spotted there's a clinic in London. Obviously, that's going to come with its complications of having treatment there [as have to travel], but I just think, as a last one-off shot, it's got amazing success rates for my age range, much higher, so perhaps I would go there.' [Mixed sex, 38-42, Private, North West]<sup>82</sup>

'All the clinics are a similar cost really. The cost is tied into the success rate of the clinic – the higher the success rate, the more likely you are to go with them, even if the cost is a bit higher. But there's not a great difference in prices – if you're spending £10k then you might as well spend £500 more if you think it's the best choice'. [Mixed sex, Under 35, Private, East of England]<sup>83</sup>

5.3 Our 2022 patient research also highlighted the importance of clinics' success rates in decision-making for certain types of patient, including those who had not previously accessed NHS-funded treatment and who were embarking on their first round of self-funded treatment.<sup>84</sup>

<sup>82</sup> CMA 2020 research (paragraph 4.2.10, page 24)

<sup>83</sup> CMA 2020 research (paragraph 4.2.10, page 24)

<sup>84</sup> CMA 2022 research (section 5.2, page 47)

'They have it [information about success rates] on the website and also on that board in the waiting room and it's one of the highest success rates in the country. It felt like we were in good hands.' [37, North, NHS clinic]<sup>85</sup>

'Success rates are a really big part of it. You're invested in the process, and you've invested so much money, of course you want it to be successful..... Whatever is going to get you the best outcome, that's where you're going to go. It wasn't about bargain hunting or shopping around. It was about what's the best thing to do, and where does the best results happen.' [30, Midlands, NHS clinic]<sup>86</sup>

- 5.4 These findings are supported by the HFEA's National Patient Survey from 2021 which found that success rates were important to 63% of respondents who had entirely self-funded their treatment when they were choosing a clinic.<sup>87</sup>
- 5.5 Our 2020 patient research also highlighted that the success rate information provided on clinics' websites is particularly important because for many prospective patients this is their main source of information when researching their clinic and treatment options.
- 5.6 Importantly, our 2022 patient research showed that it is at the research stage that clinics' success rate information, alongside price and clinic location, is particularly influential when patients are shortlisting clinics and then deciding which clinic to have treatment at. When patients booked an initial paid for consultation, they were already thinking 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 they had their first paid for consultation.<sup>88</sup> So, the information provided by clinics at the early shortlisting stage is key to prospective patients' decision making. The research also found that clinic websites are a particularly important source of information at this early shortlisting stage.
- 5.7 Clinics understand that success rates are important to many prospective patients when they are choosing between clinics. This is reflected in the prominence many clinics give to information about success rates on their

<sup>85</sup> CMA 2022 research (section 5.2, page 47)

<sup>&</sup>lt;sup>86</sup> CMA 2022 research (section 3.2.3, page 26), (section 5.2, page 47)

<sup>&</sup>lt;sup>87</sup> HFEA National Patient Survey 2021, published April 2022

<sup>&</sup>lt;sup>88</sup> 43 out of 45 participants had their initial consultation and then treatment at the same clinic – CMA 2022 Research (section 3.3.1, page 18)

websites and in other promotional materials, such as patient brochures and leaflets.

# Clinics advertise their success rates using a range of different metrics and these metrics produce different results

- 5.8 As we found when producing our Guidance, clinics advertise their success rates in different ways, which can make it difficult for prospective patients to compare them. For example, some clinics:
  - base their success rates on outcomes 'per cycle started', whilst other clinics base their success rates on 'per embryo transfer' or 'per embryo transferred'.
  - base their success rates on 'live birth' rates whilst other clinics focus on 'clinical pregnancy' rates, or 'pregnancy rates'.
  - give particular prominence to the results of particular sub-groups of patients, for example those who had PGT-A or blastocyst transfers, perhaps because the featured measure appears to be the most impressive.
- 5.9 The HFEA's code of practice encourages clinics to display the live birth rate per embryo transferred but it says this may be displayed alongside other success rate measures.<sup>89</sup>
- 5.10 In our 2021 'Patient guide on consumer rights in the fertility sector', 90 we explained what some of the key success rate measures used mean and how different measures can result in different success statistics, even though they relate to the same group of patients. Our patient guide also provided an example to illustrate some of the differences. We have replicated that table below and expanded it to include blastocyst transfers to further show how different measures can result in different statistics. 91

<sup>89</sup> Paragraph 4.10 (b) – www.hfea.gov.uk/code of practice 9th edition

<sup>90</sup> www.gov.uk/CMA fertility-treatment-a-guide-to-your-consumer-rights

<sup>&</sup>lt;sup>91</sup> This table is for illustrative purposes only and does not represent actual success rates in the UK or of any particular clinic.

Table 2 – Illustrative example of how different measures can result in different success rates based on the same data

| Clinical pregnancy measure             |     |  |          |
|--|-----|--|----------|
| Number of clinical pregnancies         | 46  | Measure clinical pregnancy rate per    | 46%      |
|  |     | cycle started                          | 46/100   |
| Number of clinical pregnancies         | 46  | Measure clinical pregnancy rate per    | 47%      |
|  |     | embryo transfer                        | (46/98)  |
| Number of clinical pregnancies         | 46  | Measure clinical pregnancy rate per    | 39%      |
|  |     | embryo transferred                     | (46/118) |
| Number of clinical pregnancies after   | 19  | Measure clinical pregnancy rate per    | 58%      |
| blastocyst transfer                    |     | blastocyst transfer                    | (19/33)  |
| Number of clinical pregnancies after   | 19  | Measure clinical pregnancy rate per    | 53%      |
| blastocyst transfer                    |     | blastocyst embryo transferred          | (19/36)  |
| Live births measure                    |     |  |          |
| Number of live births                  | 35  | Measure live birth rate per cycle      | 35%      |
|  |     | started                                | (35/100) |
| Number of live births                  | 35  | Measure live birth rate per embryo     | 36%      |
|  |     | transfer                               | (35/98)  |
| Number of live births                  | 35* | Measure live birth rate per embryo     | 29%      |
|  |     | transferred                            | (35/118) |
| Number of live births after blastocyst | 15  | Measure live birth rate per blastocyst | 45%      |
| transfer                               |     | transfer                               | (15/33)  |
| Number of live births after blastocyst | 15  | Measure live birth rate per blastocyst | 42%      |
| transfer                               |     | embryo transferred                     | (15/36)  |

<sup>\* (</sup>includes 1 set of twins counted as 1 birth per embryo transferred)

The above is based on 100 patients, having treatment at the same clinic and during the same timeframe, where there were 100 treatment cycles started resulting in 98 fresh embryo transfer procedures (of which 33 procedures were blastocyst transfers) and 118 embryos transferred (of which 36 were blastocyst embryos).

### How consumer law applies to success rates

5.11 Consumer law requires that the information clinics provide to prospective patients about their success rates must not be misleading. This means that claims about success rates must be accurate and not omit material information. Furthermore, the information must not be presented in a way that is likely to deceive prospective patients even if the information is factually correct. 92 For example, by 'cherry picking' more impressive success rates that

<sup>&</sup>lt;sup>92</sup> Where this is not the case, and this is likely to cause consumers to take a different transactional decision – such as their choice of clinic from which to buy treatment or which treatments to buy – the CPRs are likely to have been breached.

- only apply to a small, select group of patients whose results are more favourable than the overall results for patients at the clinic, without making this clear.
- 5.12 This is so that prospective patients can make fully informed decisions about their choice of clinic. It also ensures that such clinics are not competing unfairly with those clinics that are presenting their success rates fairly.
- 5.13 The HFEA collects data from all licensed clinics about their fertility treatment and outcomes. The HFEA publishes much of this data on its website, including individual clinic success rates, which the HFEA validates. The HFEA also publishes success rates showing what the national average is, so that this can be compared against individual clinic success rates.<sup>93</sup> The HFEA's code of practice provides guidance to clinics about what they need to do when providing and presenting information to patients about success rates on their websites and in marketing materials.<sup>94</sup> This covers, for example, that the information:
  - should include the most recent data available from the past three years;
  - should not highlight a high success rate that applies only to a small, select group of patients;
  - on clinic websites, should provide the national rate and like-for-like comparisons (the same year, maternal age, treatment type, etc.); and
  - should include a link to the HFEA's advice on choosing a clinic and refer to the HFEA as the source of national information on IVF clinic success rates.

#### **Compliance Review Activities**

5.14 Between December 2021 and June 2022, we reviewed a sample of clinics to see how clinic success rates are displayed and what is said about the success rates for IVF and for egg freezing. Our review initially involved assessing the success rate information available on clinic websites. In February 2022, as part of a more detailed review, we asked a further sample of private and NHS clinics to provide us with any standard additional information they may give to prospective patients about the clinics' success rates, for example in clinic brochures.

<sup>&</sup>lt;sup>93</sup> Individual and HFEA validated success rates can be found on the HFEA's choose a clinic webpages at: www.hfea.gov.uk/choose-a-clinic

<sup>&</sup>lt;sup>94</sup> Paragraph 4.10 – www.hfea.gov.uk/code of practice 9th edition

#### Summary of review findings

- 5.15 The main findings from our review of success rate information are:
  - Nearly all clinics included success rate data on their websites, although the
    measures used to calculate the success rates varied between clinics. This
    is likely to make it difficult for patients to compare clinics' success rates at
    the key shortlisting stage.
  - Only a small number of clinics included specific claims about their own success rates for treatment using frozen eggs, with clinics instead providing more general information about the factors that influence success rates.
  - We identified concerns with how some clinics display success rate information on their clinic websites and in other patient facing materials, such as clinic brochures.
  - There have been improvements in how some clinics display success rate information since we published our Guidance and the ASA published its Enforcement Notice.
  - There have been further improvements following the CMA's and ASA's direct engagement with a sample of clinics.
- 5.16 Our review found that the vast majority of clinics presented success rate information for their clinic on their websites. Only a very small number of clinics did not provide such information and all but one of these clinics instead provided a link to their clinics' profile on the HFEA website, where their HFEA-verified success results could be viewed.
- 5.17 The HFEA does not publish separate success rate information for satellite clinics. 95 We found that satellite clinics reported success rates in different ways on their websites. Where the satellite clinics were owned by a licensed clinic or were part of a wider group of licensed clinics, in some cases the patients were directed to the general success rates of the licensed clinic where the collection and transfer procedures would take place. Alternatively, the satellite clinic reported on only the results of those patients that it had treated. One of the satellite clinics that we reviewed had a relationship with more than one licensed clinic, resulting in patients being signposted to the success rates of each of the licensed clinics where the collection and transfer

<sup>&</sup>lt;sup>95</sup> The data for a satellite clinic will be included in the data for the licenced clinic which carries out the egg collection / embryos transfer.

- procedures might take place. One satellite clinic did not include any information on success rates.
- 5.18 Most clinics referenced the HFEA in the success rates information on their websites and provided a link to the HFEA website.<sup>96</sup>
- 5.19 Most of the clinics reviewed presented multiple different success rate measures. These measures varied by clinic, as did the ones to which they gave most prominence. The measure given greatest prominence most of the time was the 'Clinical Pregnancy Rate (CPR) per embryo transfer'. Clinics used other measures to further refine these results based on sub-groups of patients, for example certain age groups or patients who had PGT-A or blastocyst transfers. In some cases, the success rates of these sub-groups were given greater prominence than the clinic's other results.
- 5.20 Of the clinics that provide information on success rates, a very small number did not provide "Live Birth Rate (LBR) per embryo transferred" data anywhere on their website, as the HFEA encourages them to do in its code of practice. Instead, they provided LBR data on a 'per cycle started' or 'per embryo transfer' basis. As explained in the CMA's patient guide, the birth per embryo transferred measure gives the percentage of births (counted as 1 birth even when 2 or more babies are born) which resulted from the total number of embryos transferred. This is the preferred measure of the HFEA, who want to reduce the number of IVF cycles which result in multiple births, as these can be riskier for patients and their babies. This measure will almost always be lower than live birth rates per embryo transfer see the illustration at Table 2 above.

#### Egg freezing success rate data on websites

- 5.21 Of the clinics that we reviewed that offer egg freezing, some clinics did not make any claims on their websites about the success rates of egg freezing. Typically, these clinics explained that further information would be provided at the initial consultation.
- 5.22 Where clinics did provide information about success rates, the information provided tended to be at a general level, rather than clinic-specific data. This included statements that success rates of frozen eggs were in line with the success rates for fresh eggs for the corresponding age group at the time the

<sup>&</sup>lt;sup>96</sup> The hyperlink typically directed users to the HFEA's "Choose a Fertility Clinic" webpage.

eggs are frozen. They also often explained that the following factors impacted on success rates:

- The age at which the eggs are frozen in general the younger the patient when the eggs are frozen, the greater the chances of success.
- The number of eggs that are frozen the more eggs collected the greater the chance of success.
- 5.23 A small number of clinics included specific claims about the success rates for treatment using frozen eggs. This data was either based on cycles of treatment that had been conducted by the clinic, where the basis of the claims was set out in detail, or it was based on third party studies, mathematical calculations, or hypothetical scenarios.

### **Compliance review findings**

- 5.24 Overall, we found a mixed picture in terms of compliance with consumer law.

  For a minority of all the clinics we reviewed we found no compliance concerns in relation to their success rates information.
- 5.25 However, we found compliance issues with most of the clinics we reviewed.
- 5.26 Having reviewed a sample of clinics in more detail, we wrote to certain clinics setting out the specific compliance issues we had identified with them. We told these clinics that we expected them to review their practices and terms and make appropriate changes to ensure their compliance with consumer law. These clinics have since made several positive changes to their success rate claims. Examples of these positive changes are discussed at paragraphs 5.51 -5.53.
- 5.27 Our review found various examples of potential non-compliance with consumer law in relation to success rate information appearing on both clinic websites and in other standard information they provide to patients. This includes practices which in our view are likely to create a misleading impression of the clinic's performance as a result of the following:
  - Advertising success rate claims, including superiority claims when comparing the clinic's performance against competing clinics, without clearly identifying the basis of the claim.
  - Making claims that are based on incorrect information.
  - Citing more impressive historic success rates when more recent data is available.

 Giving undue prominence to success claims that are likely to be relevant to only a small proportion of prospective patients, without making it clear that this is the case.

Advertising success rate claims, including superiority claims, without clearly identifying the basis of the claim.

- 5.28 During the review we saw several examples of success rate claims for IVF and egg freezing where the clinics failed to clearly explain the basis of their success claims. By way of example, we saw prominent claims along the lines of "success rates up to XX%" where there was no explanation of whether the claim related to the live birth rate (LBR), clinical pregnancy rate (CPR) or pregnancy rate, or if it had been calculated against "per cycle started", "per embryo transfer" or "per embryo transferred". Some clinics also failed to identify what time-period their claims related to and whether there were any other important factors that are relevant for understanding the results. For example, whether results are for patients who had a certain type of treatment or for a particular age group.
- 5.29 Our review also identified a few instances where the clinic's description of the basis of the success rate was confusing. For example, some clinic websites explained that the advertised success rate related to the "Live Birth rate per E/T". The reference to "per E/T" can be interpreted as either "per embryo transferred" or "per embryo transfer".
- 5.30 A couple of clinics also included descriptions of the success rate claims which were contradictory. For example, graphs and tables appearing on clinics' success rate webpages were labelled as reporting on one measure but explanatory text elsewhere on the webpage stated that the same statistics related to a different measure.
- 5.31 Similarly, in relation to egg freezing, we identified a few instances where it was not made clear what the evidence base was for the success rate claims or how the success rates had been calculated.
- 5.32 We also observed clinics making success rate claims about egg freezing that were confusing. For example, for a clinic quoting a success rate based on the number of frozen eggs collected where the claim could not be reconciled with the underlying data cited by the clinic. Furthermore, some clinics' claims gave the misleading impression that the quoted success rates related directly to outcomes for patients that had undertaken fertility treatment at their clinic, rather than a study performed independently of the clinic.

- 5.33 Several clinics included information about the improved egg survival rates following vitrification as against slow freezing techniques. There was significant variation as to the reported egg thaw success rate ranging between 72% 96%. This variation appears to be because some clinics referred to their own statistics which tended to be at the lower end of that range, whereas others cited the results of third-party studies which tended to be at the higher end.
- 5.34 We are concerned that when some clinics cite high egg survival rates following the egg vitrification process, there is a risk that it may not be clear to prospective patients that the ultimate pregnancy or live birth rate is likely to be significantly lower than the figures cited. Clinics should therefore take care to ensure it is clear to prospective patients that the egg survival rate does not equate to their chance of having a baby.

#### Superiority claims

- 5.35 Our review also identified examples of superiority claims, where some clinics claimed to have the "best" or "highest" results without explaining the basis of the claim. In the examples we saw, the reference to being the 'best' tended to be based on certain measures or sub-groups of patients which appeared to present the clinic in the best light, with no clear explanation provided regarding the basis of the claims.
- 5.36 This included examples of more than one clinic from the same region purporting to have the "best" or "highest" success rates either within that region or nationwide.
- 5.37 Where material information about the basis of the claim is omitted, patients will not know whether the comparison is being made on a like for like basis. If the comparison is not made on a like for like basis prospective patients are unlikely to be able to make fully informed decisions about their choice of clinic. As illustrated at Table 2 above, patients may be misled if they incorrectly assume a clinic is reporting on the live birth rate per embryo transferred, when it is in fact reporting on another measure that results in a more impressive rate.
- 5.38 We also identified concerns with some superiority claims where it was unclear in the circumstances how the clinics making them could substantiate them. For example, one clinic claimed to be the 'best' based on their performance over a timeframe for which their competitors, or the HFEA, had yet to publish any success rate data.

#### Claims based on incorrect information

- 5.39 Our review also identified a couple of examples of clinics making success rate claims that appear to be incorrect, such as clinics:
  - advertising success rates which were not consistent with the success rates attributed to their clinic on the HFEA website;
  - advertising general claims that their success rates exceeded the national average rate, which was contradicted by the success rate information on the HFEA's website.
- 5.40 We also observed a few instances where clinics reported success rates based on the "LBR per embryo transferred" where the corresponding HFEA data or further investigation of the raw data suggested that the success rates related to other measures, such as the "CPR per cycle started" or the "LBR per embryo transfer."
- 5.41 In the above examples, we consider that the reported success rates are likely to create a misleading impression that the clinics' current performance is more impressive than it is, and that the rates compare more favourably against the national average than is the case.

Relying on historic data when more recent data is available which is more relevant to the claim being made.

5.42 Moreover, our review identified a couple of instances where some clinics advertised success rates that were based on historic data when more recent but less impressive HFEA verified success rates were available on the HFEA website. Using superseded out-of-date information about success rates in this way is likely to create a misleading impression about the clinic's more recent performance, by implying that it is more impressive than it is.<sup>97</sup>

<sup>&</sup>lt;sup>97</sup> The CMA is aware that there is a time-lag between treatment taking place and success rate data being verified by the HFEA. At the time of conducting our review the most recent verified data covered 2018 for live births and 2019 for clinical pregnancies. The CMA appreciates that it could be in patients' interests to have sight of the most recent success rates, even if they have not yet been verified by the HFEA. Using more recent data that has not yet been verified by the HFEA is not likely to breach consumer law, provided the data is accurate and information is not presented in a way that could deceive prospective patients. The CMA would also expect it to be made clear that the rates are yet to be verified.

Giving undue prominence to success claims that are likely to be relevant to only some prospective patients without making it clear that this is the case

- 5.43 We also saw several examples of success rate claims displayed prominently on clinic websites, which failed to clearly explain that they were based on only a subset of patients, whose results were more favourable than the overall results for patients at the clinic.
- 5.44 This included instances where clinics made headline claims, such as "*up to 75% success rate*" which were based on only a select sub-group of patients, for example a particular age group or patients who had had a blastocyst transfer or PGT-A. The results for such sub-groups were higher than the wider cohort of patients, but there was no explanation of this accompanying the reported success rates.
- 5.45 Such unexplained claims have the potential to mislead patients at any stage of their IVF journey, but particularly in the case of prospective patients at the research stage. This is the stage at which patients are generally reviewing clinics' success rates, and they are unlikely to know yet whether the results are likely to be relevant to them. For example, when choosing a clinic, even if the patient understood the meaning of a blastocyst transfer, they would not know whether they would have any embryos that developed to blastocyst stage. Therefore, a success rate measured from blastocyst transfer, which was higher than the applicable success rate measured per embryo transferred, could mislead them.
- 5.46 In the above scenarios we are concerned that the success rate claims may create the misleading impression that the advertised rate is more broadly applicable to a wider group of patients and so unduly influence prospective patients' decisions to buy treatment from the clinic.
- 5.47 Some of the examples provided in paragraphs 5.27 to 5.46 may be a result of clinics not paying sufficient attention to the accuracy of the information presented on their website, rather than a deliberate attempt to gain a competitive advantage over other clinics. Irrespective of whether there is any intentionality, such practices remain examples of potential non-compliance with consumer law.

#### Clinics based overseas

5.48 Our targeted review of the websites of a small number of overseas fertility clinics that market their services to UK patients found that most provided information on their success rates. Where clinics did display success rates,

there was significant variation in the measures used to calculate them, and how the information was presented on the clinic websites.

#### 5.49 We saw success claims that:

- focused on the success rates of particular groups of patients, such as
  those patients undergoing IVF that had also purchased PGT-A or those
  patients undergoing IVF with donor eggs, without explaining how many of
  the clinics' patients this related to.
- failed to clearly explain what measures had been used to calculate the success rates, for example whether the rate was based on per cycle started, per embryo transfer or per embryo transferred, or what timeperiod the claim covered.
- made vague superiority claims such as "above international standards" without referring to any supporting evidence, or referring to evidence that did not support the claim.
- 5.50 Furthermore, unlike in the UK, it is often the case that the success rates for overseas clinics are not independently verified, making it difficult for patients to check the accuracy of any claims.

# Improvements in how clinics provide success rate information

- 5.51 As well as the examples of potential non-compliance summarised above, we also found that several clinics had made improvements following the publication of the Guidance and the ASA's Enforcement Notice. As with our review of clinic pricing practices we could also see that those clinics that we reviewed in detail were continuing to make changes during the course of our reviews. Examples of the changes include:
  - being more transparent about the measures that have been used to calculate the success rates;
  - providing clearer explanations of the differences between the available measures, and the potential impact the chosen measure may have on the resulting success rates;
  - removing unexplained success rate claims which appeared to exaggerate the clinic's performance, including when making superiority claims compared to other clinics;

- updating success rate data to reflect more recent statistics, which better reflects the clinic's current performance;
- giving greater prominence to the raw data behind the success claims, thereby helping prospective patients to assess how much weight should be given to the claim.

Clinics have made positive changes following our letters outlining compliance concerns

- 5.52 As explained at paragraph 5.26 above, we wrote to some of the sample clinics we reviewed in detail to highlight specific concerns we had identified with their success rate claims. We told the clinics that we expected them to review their practices and make appropriate changes to ensure their compliance with consumer law.
- 5.53 All the clinics we contacted have subsequently made changes to address compliance concerns we highlighted to them. We welcome the constructive approach adopted by clinics. We are continuing to engage with some of the clinics to resolve a small number of outstanding issues. The changes made include (in addition to several of the examples listed above):
  - Clinics removing or amending success rate claims on their websites to ensure claims that relate to only a small subset of patients are not given undue prominence.
  - Clinics removing success rate claims that could not be substantiated.
  - Clinics removing success rates that were based on incorrect data.

#### Recommendation

5.54 We strongly recommend that clinics review their success rate information, and any success rate claims they make, in the light of the compliance concerns identified in this chapter, and take any corrective action necessary as a matter of priority. Clinics should not assume because we have not written to them directly to highlight concerns that their practices are compliant with consumer



# 6. Information about the benefits and risks of treatment add-ons

#### Introduction

6.1 This chapter begins by defining treatment add-ons. It then briefly explains some of the controversy surrounding their sale and the work by the HFEA in this area. Drawing on our patient research, the chapter provides an overview of why treatment add-ons can be attractive to patients. It then explains in brief how consumer law applies, before summarising the findings from this part of the compliance review.

# What are they?

6.2 Treatment add-ons are described on the HFEA's website<sup>99</sup> 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' (our emphasis). Treatment add-ons include genetic tests, surgical interventions, drugs, and equipment. Some add-ons have been around for many years, while others are more recent.

# What do they cost?

- 6.3 Some treatment add-ons can be particularly expensive, especially so when patients buy several add-ons. The price advertised by different clinics for the treatment add-ons also varies significantly. For example, listed below are the lowest and highest prices we saw advertised for a selection of treatment add-ons:100
  - Endometrial Receptive Array (ERA) from £900 to £1,500
  - EndomeTrio<sup>101</sup> from £1,450 to £3,100
  - Reproductive Immunology (IVIG) from £1,270 to £2,890
  - Assisted Hatching from £380 to £555

<sup>99</sup> www.hfea.gov.uk/treatments/treatment-add-ons

<sup>&</sup>lt;sup>100</sup> Based on our detailed review of a smaller sample of clinics

<sup>&</sup>lt;sup>101</sup> Comprising ERA, Endometrial Microbiome Metagenomic Analysis (EMMA) and Analysis of Infectious Chronic Endometritis (Alice)

- Endometrial scratch from £150 to £400
- 6.4 The advice on the HFEA website 102 to patients is that they may wish to think about whether it might be more effective and/or affordable to pay for multiple routine proven treatment cycles, rather than spending large sums of money on a single treatment cycle with treatment add-ons that haven't been proven to be effective at increasing the likelihood of having a baby.

# Why are they controversial?

- 6.5 Treatment add-ons can be controversial. For example, there have been media reports claiming that patients are being exploited or mis-sold treatment add-ons, and that patients are wasting their money on unproven treatments. 103 That controversy also exists within the fertility sector, where there is a wide divergence of views about the use and effectiveness of some of the treatment add-ons.
- 6.6 The HFEA has undertaken work, and continues to do so, to improve the marketing and selling of treatment add-ons as well as providing information about them to patients. For example:
  - The HFEA has published information on its website about twelve treatment add-ons, each of which has been given a traffic light rating <sup>104</sup> based on the existence and strength of any clinical evidence, in the form of high-quality randomised control trials (RCTs), showing whether they are effective at improving the chances of having a baby for most fertility patients <sup>105</sup>. Furthermore, the HFEA's information acknowledges that some treatment add-ons may have other benefits for certain patients, such as reducing the risk of having a miscarriage.
  - In 2019, the HFEA agreed a Consensus Statement<sup>106</sup> with 10 professional and patient fertility bodies, which set out principles to ensure

<sup>102</sup> See footnote 99

 <sup>103</sup> For example: www.bbc.co.uk/news/wales-60467612, www.dailymail.co.uk/news/IVF-clinics-selling-ineffective-add-treatments-desperate-parents-face-fines.html 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
 104 This is not a complete list, the HFEA say that additional treatment add-ons are likely to be rated over time.
 The HFEA's traffic light system gives a colour rating of red, amber or green. Currently 7 are rated red and 5 are rated amber.

<sup>&</sup>lt;sup>105</sup> The HFEA explain that: (i) an amber rating means there is **conflicting evidence from RCTs** to show that the add-on is effective at improving the chances of having a baby for most fertility patients. This means that the evidence is not conclusive and further research is required, and the add-on should not be recommended for routine use; and (ii) a red rating means there is **no evidence from RCTs** to show that it is effective at improving the chances of having a baby for most fertility patients.

<sup>106</sup> www.hfea.gov.uk/Treatment Add-Ons Consensus Statement

add-ons are offered responsibly in clinical practice. At the time the Consensus Statement was published, it was said to be 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 pregnancy, and the fact that many patients feel they must do anything to improve the possibility of success'. 107

Every 12 months, the HFEA's Scientific and Clinical Advances Advisory
 Committee (SCAAC) and an independent expert reviewer of the quality of
 evidence, review the available research for each treatment add-on in the
 HFEA's traffic-light rated list to determine whether the evidence base has
 changed. The minutes of this decision-making process can be found on
 the HFEA's website. 108

# Why might treatment add-ons be attractive to patients?

- 6.7 Our 2020 patient research<sup>109</sup> highlighted some of the reasons patients bought treatment add-ons:
  - Many felt that, in the context of the high cost of IVF treatment, some treatment add-ons were relatively affordable. As these participants explained, since they had already invested large sums of money in this treatment, they wanted to try everything they could, even when sceptical or unsure about the benefits of the treatment. They worried that if they were unsuccessful, they may regret not trying something 'just' because of an extra £200- £300, a sum they felt was dwarfed by the thousands they were already paying for IVF.
  - Some participants who had experienced multiple unsuccessful IVF cycles wanted to keep trying different approaches in the hope that one of them may work. They reported that some clinics also had a similar approach to test and try additional treatments in subsequent cycles.

'I also had Intralipids – a type of drip. I thought it was a bit hocuspocus, but I did it anyway. The research on it was inconclusive but we didn't have time to wait until it was proven. We thought we'd try it as it

<sup>&</sup>lt;sup>107</sup> www.hfea.gov.uk/press-releases/2019/ consensus statement

<sup>&</sup>lt;sup>108</sup> For further details - https://www.hfea.gov.uk/about-us/our-authority-committees-and-panels/scientific-and-clinical-advances-advisory-committee-scaac/

<sup>109</sup> https://assets.publishing.service.gov.uk/media/5fa01b30e90e070420702a1b/IVF Research Final Report.pdf

wasn't a ridiculous amount of money'. [Same sex, 38-42, Private, South East]<sup>110</sup>

'They just told me what it [scratch] was and how it could be beneficial, so at that point it's like, it's only an extra £250, we might as well. If it doesn't work, then you're going to think, well, if only I had spent that £250 extra and it could have worked.' [Mixed sex, under 35, Private, E England]<sup>111</sup>

'There's no proof of success, but it's a peace-of-mind thing.' [Mixed sex,35-39 years old, Private, North West]<sup>112</sup>

'I remember him [the consultant] saying, in terms of how beneficial it is, that it was difficult to say, but there's no disadvantages, so you might as well, just in case it does work. [Male participant] I remember challenging him on that a little bit, and he said the jury's out, 50/50. He said it wouldn't harm it, and there was no reason not to. It was a small amount of money, which doesn't mean anything when you're trying to have a baby.' [Mixed sex, Under 35 years old, Private, East Midlands] 113

'The add-ons get complicated because of the research involved. You're left wondering whether to try it or not. The evidence doesn't always stack up, but you're willing to try anything if you think it would make a significant difference. A good thing about the [third party finance provider multi-cycle] packages is that they bundle a lot of that in, so it takes the decision away from you.' [Mixed sex, 43+, Private, East Midlands]<sup>114</sup>

#### How do patients learn about treatment add-ons?

6.8 Our 2020 patient research found that most participants had learned about treatment add-ons from clinic websites before engaging with the clinic or, after engaging with the clinic, from clinic brochures, price lists shared with them during consultations or from consultants. A smaller group of participants read or heard about these treatments independently of the clinic they used. These participants explained how they heard positive comments about particular

<sup>&</sup>lt;sup>110</sup> CMA 2020 research (paragraph 4.3.33, page 45)

<sup>&</sup>lt;sup>111</sup> CMA 2020 research (paragraph 4.3.33, page 45)

<sup>&</sup>lt;sup>112</sup> CMA 2020 research (paragraph 4.3.32, page 44)

<sup>&</sup>lt;sup>113</sup> CMA 2020 research (paragraph 4.3.32, page 44)

<sup>&</sup>lt;sup>114</sup> CMA 2020 research (paragraph 4.3.24, page 40)

- treatment add-ons from friends and family who used them or other patients who discussed them on fertility forums.
- 6.9 Our 2022 patient research found that clinic websites remain the top source of information for patients. 115 It also shows the importance of clinic website information in the decisions that patients make early on about their choice of clinic and what treatments to buy. These decisions can then be further influenced, and strongly so, by the advice of their consultants. As the 2022 patient research report describes:

'All patients went into their consultation with at least some idea of the type of treatment(s) they wanted to buy. This was either based on their own research or on their experiences of/ results from prior rounds of treatment. However, all patients described placing huge trust in and reliance on their consultants to recommend the best treatment options for them. Following the consultation, these recommendations were strongly weighed against what patients had previously been considering. This was true even amongst those who went into consultations with strong convictions about which treatment(s) they wanted to buy.' 116

# How consumer law applies to treatment add-ons

6.10 Consumer law requires that existing and prospective patients are provided with material information at the time that they need it, and in a format that is clear and easy to understand. In our view this includes information about the risks, evidence base and the HFEA's information about treatment add-ons, along with signposting to the HFEA's website. This is so that the decisions patients make about whether to buy an add-on treatment are properly informed. Where the presentation of certain prescribed information, or the omission of material information gives rise to a misleading impression that is likely to cause consumers to take a different transactional decision – such as whether to buy a treatment add-on– the CPRs are likely to have been breached.

<sup>&</sup>lt;sup>115</sup> The HFEA's National Patient Survey also says that of the 1,233 patients surveyed the top source of information for 73% was clinic websites - National Patient Survey 2021 | HFEA <sup>116</sup> CMA 2022 research (section 3.1.2, page 19)

<sup>&</sup>lt;sup>117</sup> See paragraphs 3.9 to 3.61 of the CMA's guidance covering the CPRs and CCRs and Table 1 (Page 32) of the CMA's guidance

- 6.11 The HFEA's code of practice<sup>118</sup> also clearly states that **before** treatment is offered, information should be provided about the fertility treatments available, including any treatment add-ons which may be offered and the evidence of effectiveness supporting their use and the applicable risks. Further, that any such information should explain that 'treatment add-ons' refers to the technologies and treatments listed on the treatment add-ons page of the HFEA website.
- 6.12 We would expect any claims relating to the success rates of particular treatment add-ons, whether made by clinics directly or in third-party-produced information provided by clinics to patients, to be accompanied by a clear and prominent explanation of the basis on which the claim is made, including:
  - The time period the claim relates to;
  - What measure is being used (i.e., per embryo transfer, per embryo transferred or per cycle); and
  - What criteria have been used to determine the group of patients to which the success rate applies (e.g., age, location, medical conditions, stage of treatment reached etc.).
- 6.13 Failing to provide such information may create a misleading impression about the benefits of a particular add-on treatment which may influence patients' choice of clinic and/or the treatments they decide to buy. Patients may also be misled where clinics extol the benefits of particular treatment add-ons but do not mention the clinical evidence base for them or any of the risks that may be associated with the treatment add-on.
- 6.14 We are aware that some stakeholders would like to see the advertising and selling of certain treatment add-ons banned. There are no express provisions within consumer law that empower the CMA to ban any goods or services in any sector. The Guidance concentrates on what is within the remit of the CMA and so explains what the CPRs require by way of the presentation and provision of information in order to avoid engaging in misleading commercial practices, as well as guidance on avoiding other types of unfair commercial practice. <sup>119</sup>

<sup>&</sup>lt;sup>118</sup> hfea.gov.uk/Code of Practice - 9th edition – paragraphs 4.7 (d), 4.8 and 4.9 refer

<sup>&</sup>lt;sup>119</sup> The term 'commercial practice' is broad in scope and time, and includes any practice by a trader directly connected with the promotion, sale or supply of goods or services to consumers. <sup>120</sup> These add-ons were chosen because they all carry risks and are currently rated red on the HFEA's traffic light rating list, except endometrial scratch which is currently rated amber

#### **Compliance Review Activities**

- 6.15 Between December 2021 and June 2022, we reviewed a sample of clinics' websites to see if they advertised the following treatment add-ons. 120 If they did, we then assessed what the sample clinics said about the risks of these treatment add-ons, the clinical evidence base and whether there were any references and signposting to the HFEA and its information about treatment add-ons. The particular treatment add-ons we looked at as part of our review were as follows:
  - Assisted hatching
  - PGT-A
  - Endometrial scratch
  - Reproductive Immunology<sup>121</sup>
  - ERA
- 6.16 In February 2022, as part of a more detailed review, we asked a further sample of private and NHS clinics to provide us with any additional information they may give to prospective patients about these specific treatment add-ons, for example in patient leaflets and brochures.
- 6.17 Overall, we found a mixed picture in terms of compliance with consumer law. For a small minority of the clinics we reviewed we found no compliance concerns in relation to the information they provided on treatment add-ons. This was because they did not offer any of the treatment add-ons under review on their websites or in the patient information supplied by those clinics we requested further information from or because they provided patients with material information about the risks, benefits and the nature of the clinical evidence base for these treatment add-ons, with clear signposting to the HFEA website.
- 6.18 We found compliance issues with the majority of the clinics we reviewed, albeit that in some cases these were relatively minor. Following our more detailed review, we wrote to certain clinics setting out the specific compliance issues we had identified with them. We told these clinics that we expected them to review their practices and terms and make appropriate changes to ensure their compliance with consumer law. These clinics have since made

<sup>&</sup>lt;sup>120</sup> These add-ons were chosen because they all carry risks and are currently rated red on the HFEA's traffic light rating list, except endometrial scratch which is currently rated amber

<sup>&</sup>lt;sup>121</sup> Reproductive Immunology in this review, consistent with the HFEA's traffic light rating system, comprises of Steroids, Intralipids and Intravenous Immunoglobulin (IVIG)

- positive changes including in relation to information they provide to patients about the risks, clinical evidence base and the HFEA's traffic light system. Examples of these changes are discussed at paragraph 6.31.
- 6.19 We know, for example through patient contact and from our 2020 patient research, that some patients might be offered treatment add-ons during conversations and in consultations with clinic staff before or during their treatment. As explained in paragraph 3.4, we have not been party to what is said to patients in private medical conversations and consultations, so we have not been able to consider this part of the patient journey in our compliance review.

# **Review Findings**

- 6.20 In summary, the key findings from our review of the information provided about treatment add-ons are that:
  - The majority of the clinics that we reviewed advertised on their websites
    one or more of the five treatment add-ons that we focused on (see
    paragraph 6.15). Several clinics did not advertise any of the five treatment
    add-ons and only a few clinics advertised all five treatment add-ons on their
    websites.
  - The treatment add-ons advertised by most of the clinics we reviewed were PGT-A, advertised on over half of the websites, followed by endometrial scratch which was advertised by a little over half of the clinics reviewed.
  - ERA, the newest addition to the HFEA's RAG traffic light rating, was advertised the least, with about a quarter of the websites reviewed advertising this treatment. The next least advertised treatment add-ons, each advertised on about a third of the websites we reviewed, were assisted hatching and reproductive immunology.<sup>122</sup>
  - In a few instances, one or more of the five treatment add-ons was only referred to on the clinic's price lists, with no further information provided.
  - Certain treatment add-ons were included by a few clinics and third-party providers of multi-cycle packages, as part of a treatment package.

<sup>&</sup>lt;sup>122</sup> Some of the websites of the sample of clinics that we reviewed indicated that they only offered one of the three treatments/medication included under the heading of RI on the HFEA's website and as considered by us in our review, for example only steroids and not IVIG or Intralipids.

- We have seen good examples of compliance by clinics in some of the information they provide about particular treatment add-ons, and we saw some improvements being made following the publication of our Guidance.
- During the reviews we identified various examples of potential noncompliance by some clinics. This included where clinics:
  - failed to provide information about the risks associated with certain treatment add-ons
  - failed to provide information about the clinical evidence base for certain treatment add-ons
  - provided information containing claims that linked success to improving implantation, pregnancy and/or live birth rates to the use of certain treatment add-ons without explaining the basis of the claims.
  - failed to mention the HFEA's information on add-on treatments and/or provided inadequate signposting to the HFEA.
  - misrepresented the views of the HFEA.

Failing to provide information about the risks of certain treatment add-ons

- 6.21 Some treatment add-ons, as explained on the HFEA's website, carry certain risks to the patient or to their embryos. These risks vary in their potential severity, from minor to serious. For example, according to the HFEA:
  - Endometrial scratch 'some patients experience pain and blood loss; it is not common for patients to have an infection after the scratch. There is a small risk of an infection within the cervix before 'scratching', this may cause the infection to spread into the uterus.' 123
  - Reproductive Immunology (Steroids) 'Common side effects include weight gain, restlessness, sleep disturbance, sweating, muscle pain/weakness and abdominal discomfort. Steroids inhibit the immune system so put patients at increased risk of infections, from the minor to the very serious. These infections can cause considerable harm not just to the patient but also to the baby. Other serious side effects are rarer but include fluid retention (swelling in the hands or ankles), breathlessness, high blood

<sup>123</sup> www.hfea.gov.uk/treatment-add-ons/endometrial-scratching

sugar, high blood pressure, mood/behaviour changes, visual disturbance, abnormal bruising/bleeding and risk of peptic ulcer. There is also the risk of allergic reactions which range from minor rashes to serious anaphylaxis with facial swelling and difficulty breathing 124

6.22 We found that the majority of clinics in our review sample, whilst highlighting the potential benefits of certain treatment add-ons, either did not mention any of the risks associated with those treatment add-ons, or only referred to some of the risks. We found this to be the case on clinic websites as well as in other patient-facing materials, such as patient leaflets. Several clinics, when advertising some of the treatment add-ons, only referred to risks in a general way, saying these would be discussed later, if necessary, with a consultant. Such practices could breach consumer law, see paragraph 6.10-6.14.

Making claims that link overall success rates or results to the use of certain treatment add-ons without any explanation of the basis on which the claims were made.

- 6.23 We found that a few clinics provided patients with information that contained claims that linked success to improvements in implantation, pregnancy and/or live birth rates, to the use of particular add-on treatments. For example, quoting success rates that linked those rates to the use of a particular treatment add-on or referring to patients who had had previous unsuccessful treatment being successful after having a particular treatment add-on.
- 6.24 We found that the basis of such claims was not explained, which could breach consumer law and raised concerns as to whether such claims were in fact supported by robust evidence. Such claims are likely to give patients the impression that their own chances of success will be improved by having this treatment, which may be misleading if those claims cannot be substantiated.

Failing to mention the HFEA's information on treatment add-ons or giving inadequate signposting to the HFEA

6.25 We found that when advertising treatment add-ons most clinics we reviewed failed to make any mention of the HFEA and its information about treatment add-ons on their websites. We also found that several of the clinics we requested information from, failed to mention the HFEA and its information about treatment add-ons in some of the information it provided to patients, for

<sup>124</sup> www.hfea.gov.uk/treatment-add-ons/immunological-tests-and-treatments-for-fertility

example in patient leaflets. The HFEA's traffic light rating list for treatment add-ons includes, for example, information about the clinical evidence base for each treatment in the form of high-quality RCTs as well as information about whether there is conflicting evidence and the results of past and more recent studies. For example, according to the HFEA:

- Assisted Hatching 'Is not recommended because it has not been shown to improve pregnancy rates. NICE also says that further research is needed to find out whether assisted hatching influences birth rates and to examine the consequences for children born as a result of this procedure. Some clinics believe assisted hatching can lead to higher birth rates in specific subgroups of patients. There is however no high-quality evidence to support the use of assisted hatching for any patient.'125
- ERA 'One RCT has been performed to study the effectiveness of ERA at increasing a patient's chances of having a baby. The outcomes of the study were promising but the results did not prove that ERA made a true difference to the patient's chances of having a baby and we can't be certain of their reliability.' 126
- Reproductive immunology (Intravenous immunoglobulin) 'There is no evidence to support the use of intravenous immunoglobulin as an add-on in fertility treatments.' 127
- 6.26 We consider the HFEA's information about treatment add-ons, with clear signposting to the HFEA's website, 128 to be material information under the CPRs. The omission of such information could cause patients to take a different transactional decision in particular in relation to whether to buy that treatment add-on. Such practices could breach consumer law, see paragraph 6.10-6.14.

Misrepresenting the views of the HFEA

6.27 A few clinics misrepresented the views of the HFEA by referring to 'the HFEA's views' or 'comments' and then not accurately reflecting what the HFEA had said about a particular treatment add-on, or omitting material information provided by the HFEA, for example about the risks of certain

<sup>125</sup> www.hfea.gov.uk/treatment-add-ons/assisted-hatching

<sup>126</sup> www.hfea.gov.uk/treatment-add-ons/endometrial-receptivity-array-era

<sup>127</sup> www.hfea.gov.uk/treatment-add-ons/immunological-tests-and-treatments-for-fertility

 $<sup>^{128}</sup>$  See paragraphs 3.9 to 3.61 of the CMA's Guidance covering the CPRs and CCRs and Table 1 (Page 32) of the CMA's Guidance

treatment add-ons. This could mislead patients as to the HFEA's views on the efficacy of or risks associated with, the treatment add-on in question. Where material risk information is omitted, it could lead patients to think that the HFEA does not have any concerns about the risks for certain treatment add-ons when this is not the case. This may affect the decisions patients go on to make as to whether to buy certain treatment add-ons.

#### Clinics based overseas

- 6.28 Our targeted review of the websites of a small number of overseas fertility clinics that market their services to UK patients found that treatment add-ons were not commonly advertised.
- 6.29 We found that the few overseas clinics that did advertise treatment add-ons mentioned the potential benefits of those treatments but information about any risks associated with them was rarely provided.
- 6.30 The few clinics that advertised treatment add-ons also did not advertise a price for these treatments. One clinic website stated that costs would be discussed with the patient at the consultation with the clinic.

#### Improvements in how clinics provide information about treatment add-ons

- 6.31 Following the publication of the CMA's Guidance and the ASA's Enforcement Notice, we have seen a number of positive changes in clinics' practices. We could also see that those clinics that we reviewed in detail were continuing to make changes during the course of our reviews. In particular, we have seen examples of:
  - Clinics adding information about the risks associated with treatment addons to the information provided to patients.
  - Clinics including links to the HFEA information on treatment add-ons webpages.
  - Clinics adding information about the clinical evidence base for particular treatment add-ons to the information provided to patients.

# Clinics have made positive changes following our letters outlining compliance concerns

6.32 As explained at paragraph 6.18 above, we wrote to some of the sample clinics we reviewed in detail to highlight concerns we had identified with their information about specific treatment add-ons.

- 6.33 All the clinics we contacted have subsequently made changes to address compliance concerns we highlighted to them. We welcome the generally constructive approach adopted by clinics. We are continuing to engage with a couple of the clinics to resolve a small number of outstanding issues.

  Examples of the types of changes include:
  - Adding information about the HFEA's views about treatment add-ons to the relevant clinic webpages;
  - Updating webpages to provide additional information about the potential benefits and risks of certain treatment add-ons;
  - Replacing third party patient leaflets, that make potentially misleading claims about success rates resulting from the use of certain treatment addons, and do not reference the HFEA, with clinics' own leaflets which will include information about the clinical evidence, risks and HFEA's views;
  - Providing clearer information about the basis for claims about the success rate of certain add-ons.

#### Recommendation

6.34 We strongly recommend that clinics review the information they provide on treatment add-ons, in the light of the compliance concerns identified in this chapter. They should take any corrective action necessary as a matter of priority. Clinics should not assume because we have not written to them directly to highlight concerns that their practices are compliant with consumer law. Moreover, whilst we have not been able to assess what is said about treatment add-ons to patients during their private conversations with clinics (see paragraph), clinics need to make sure that what is said during those discussions is compliant with consumer law too. Failure to comply with consumer law could result in the CMA, or others, taking enforcement action. 129

<sup>129</sup> See CMA Guidance - paragraph 1.26

# 7. Contract Terms

#### Introduction

- 7.1 When we began our work in the fertility sector stakeholders told us that many clinics did not have what they considered to be terms and conditions. Some also told us that the usefulness of terms and conditions to prospective patients was something that not all clinics had considered.
- 7.2 This chapter begins by explaining why terms and conditions are important. It then explains in brief how consumer law applies, before summarising the findings from this part of the compliance review.

#### Terms and conditions between clinics and patients

- 7.3 Where a patient is paying for goods or services there will be a contract between the clinic and patient which covers the terms of the service or nature of the goods to be supplied. This is the case even when the service is a medical one and the consumer is also a patient. The CMA would normally expect clinics' contracts with patients to be in writing.
- 7.4 A cycle of treatment may involve a patient entering into different contracts with the same clinic at different stages of the patient journey. For example, a contract for the initial consultation and then a further contract later on for the provision of treatment. Some patients may enter into a contract with more than one clinic (e.g. a satellite clinic for diagnostic services and later a licensed clinic for egg collection and transfer).

#### How consumer law applies to contract terms

- 7.5 Unfair terms legislation (Part 2 of the CRA 2015) aims to protect consumers against unfair contract terms. It applies to the vast majority of terms applicable to clinic-patient interactions and therefore all such terms are potentially subject to a test of unfairness under the legislation.
- 7.6 It is important that clinics use terms that are fair and transparent<sup>130</sup> in order to comply with Part 2 of the CRA. As set out in the Guidance, patients are likely to be in a relatively weak position when compared with a clinic for a number of reasons, including because they are likely to be unable or reluctant to stop

<sup>&</sup>lt;sup>130</sup> Section 68 of the CRA provides that a term is transparent if it is expressed in plain and intelligible language and is legible. Important terms must be prominently highlighted to consumers or those terms might not meet the transparency requirement.

treatment once treatment has started. The likely vulnerable circumstances of patients, at the time the contract is agreed, and when subsequently being enforced, is an important consideration in the legal assessment of fairness. Contract terms will be unfair if they put patients at an unfair disadvantage.<sup>131</sup>

7.7 Clinics also have obligations under the CCRs to give or make available certain 'pre-contract' information to patients before they are bound by a contract with the clinic. 132 In the case of 'distance contracts' this pre-contract information includes information about the patient's cancellation rights under the CCRs. 133 The CRA 134 provides that the pre-contract information provided by a clinic to a patient is to be treated as a term of the contract subsequently entered into.

#### Compliance review activities

7.8 As part of the review, we examined a sample of clinics' terms and conditions that are used with their patients. Some of these terms and conditions were provided directly to the CMA by clinics in response to a request for copies of standard information provided to patients. We also reviewed a sample of clinic websites to identify whether clinics' terms and conditions are publicly available. Our findings are set out below. We have also written to certain clinics to highlight specific concerns we had identified with the terms that they use with their patients.

# **Review Findings**

#### Summary of findings:

- 7.9 Positively, we have seen an increase in the use of written terms since we published the Guidance. However, our review identified some terms being used by clinics which we consider may be unfair under Part 2 of the CRA. We are concerned that these terms have the potential to unfairly disadvantage patients. We have also identified examples of clinics' practices that could breach the CCRs. In summary, we have found examples of terms that:
  - misrepresent or purport to limit patients' statutory cooling-off rights;

<sup>&</sup>lt;sup>131</sup> Section 62(4) of the CRA provides that a term is unfair if, contrary to the requirement of good faith, it causes a significant imbalance in the parties' rights and obligations under the contract to the detriment of the consumer.

<sup>&</sup>lt;sup>132</sup> See paragraphs 3.54-3.61 of the CMA's Guidance.

<sup>&</sup>lt;sup>133</sup> See Table 2 at paragraph 3.57 and footnote 62 of the CMA's Guidance.

<sup>&</sup>lt;sup>134</sup> Section 50(3).

- allow clinics to charge cancellation fees or retain prepayments in circumstances where it may be unfair to do so;
- give clinics wide discretion to vary the price in circumstances where the treatment plan has not changed;
- unfairly restrict the time period during which treatment must be taken;
- exclude or limit clinics' liability under the contract in a potentially unfair way;
- permit clinics to transfer patients' rights under a contract to a different clinic and which could be open to challenge as unfair if, for example, the transfer could result in unwanted changes to the patients' treatment.

## Not providing contract terms in a clear way

- 7.10 Entering into a contract to purchase fertility treatment is a significant decision for patients, both financially and emotionally. We are concerned that some clinics still do not have clear terms and that patients may not be enabled to fully understand their rights and obligations before agreeing to purchase fertility treatment.
- 7.11 Often terms are spread across multiple documents and webpages, and we identified for some clinics inconsistencies in how rights and obligations are described where they are contained in multiple places.
- 7.12 We are concerned that some clinics are still not giving patients important information about terms or copies of contracts at early stages of decision-making, for example when patients are researching clinics and treatment options. We have seen that some clinics have separate contract terms for initial consultations and for the fertility treatment itself. Patients may only receive information about terms for the fertility treatment once they have had their initial consultation and, as identified in our 2022 patient research, are already minded to have treatment at the clinic. 135 We can therefore see benefits in clinics making their terms available on their websites so that patients can choose to consider information about cancellation, refund and payment terms of fertility treatment before they commit to the cost of an initial consultation or initial diagnostic tests.
- 7.13 The contract terms that we have seen vary greatly in how user-friendly and comprehensible they are, and we consider that some are likely to fall below

<sup>&</sup>lt;sup>135</sup> CMA 2022 research (section 5.3, page 52)

the standards of transparency required under consumer law. Terms are more likely to meet the requirement for transparency where clinics set out all the rights and obligations arising under the contract in one document and in plain and intelligible English. <sup>136</sup>

#### Cancellation and Refund Terms

## Statutory cooling-off rights

- For distance and off-premises contracts for patient-funded fertility services e.g. those entered into between clinics and consumers online or by telephone, or at another location such as a trade show, patients have statutory coolingoff rights. Under the CCRs, the patient has the right to cancel the contract within a 14-day cancellation period which normally runs from the date the contract was entered into. Clinics should not start providing services within the 14-day cancellation period unless the patient expressly requests that they do so. Where services are provided within the cancellation period, the patient may still exercise their right to cancel, and they will only be liable to pay for the services received if they expressly requested them to start before the end of the cancellation period, 137 and the clinic had provided the related precontract information required under the CCRs. If these requirements are fulfilled, patients will be entitled to a partial refund proportionate to the services not yet provided, and they will only lose their right to cancel before the end of the cancellation period if the agreed services have been fully provided at their express request. 138
- 7.15 We have seen examples of clinics misrepresenting or purporting to limit patients' statutory cooling-off rights, for example, by suggesting that if the patient requests services to begin within the 14-day period they lose their cancellation and refund rights altogether. The right to cancel under the CCRs cannot be excluded, and any term purporting to do so is likely to be unfair and unenforceable.
- 7.16 This issue can be further exacerbated by a lack of clarity where clinics do not make clear which terms apply to which aspect of their services. For example, where the cooling-off rights only apply to a clinic's contracts for an initial

<sup>&</sup>lt;sup>136</sup> See 2.42-2.62 of CMA37 for more information on transparency requirements under the CRA.

<sup>&</sup>lt;sup>137</sup> In the case of an off premises contract, this request is only valid if it was provided by the customer on a 'durable medium.'

<sup>&</sup>lt;sup>138</sup> Regulation 36 of the CCRs.

consultation but not to contracts for subsequent fertility treatment <sup>139</sup> and the clinic fails to provide cancellation terms that clearly differentiate between the two. As explained in the Guidance, we expect clinics to direct patients to the terms that are directly relevant to their particular stage of treatment.

#### Initial Consultations

- 7.17 We found during our review that some clinics have cancellation terms for initial consultations (and associated scans and tests where these are offered as a package) which permit them to charge fees, or retain prepayments, in circumstances where the patient decides not to go ahead with the contract and receives no services. Some clinics appear to charge cancellation fees in these circumstances on a tiered basis depending on how much notice is given of the cancellation. For example, charging anywhere between 25 per cent to 100 per cent of the initial consultation fee depending on the number of days' notice given with the fee increasing closer to the date of the appointment. We have also seen examples where terms provide for clinics to charge patients substantial fees in the event of rescheduling appointments.
- 7.18 Such terms raise potential fairness concerns under the CRA. As noted in paragraph 5.38 of the Guidance, terms which set out a clinic's cancellation charges or applicable refunds when patients cancel are more likely to be fair where they reflect an amount intended to cover the clinic's actual losses resulting directly from the cancellation (e.g. costs already incurred or net loss of profit). A relevant consideration is also whether the clinic could fill the cancelled appointment slot with another patient booking during the notice period i.e. whether clinics can mitigate their loss.
- 7.19 An example of a term that may be open to challenge is: "We reserve the right to charge you a fee if you cancel the initial consultation. The amount of this cancellation fee will be the price of the initial consultation."
- 7.20 In addition, clinics should note that patients' statutory cooling-off rights (outlined in paragraph 7.14 above) will take precedence over cancellation rights and refunds set out in the contract where they conflict, and clinics should not seek to restrict patients' rights in this regard.

<sup>&</sup>lt;sup>139</sup> We understand that most contracts for initial consultations, scans and tests are likely to be 'distance contracts' concluded by telephone or online. Whereas the contract for treatment itself may be entered into following a face-to-face consultation and is therefore less likely to be a distance contract (but could be in certain circumstances, for example in the case of a patient who concludes a new contract for fertility services without any prior face-to-face contact).

#### Refund terms – single cycle

- 7.21 We found that clinics' refund policies vary significantly, and some refund policies are more generous than others. All clinics we looked at had policies or terms making provision for refunds in some circumstances where a treatment cycle was cancelled before egg collection, which is in line with our Guidance. For example, if the clinic withdraws treatment for medical reasons, or if the treatment cycle stops before an egg collection procedure takes place. Some clinics have more generous refund terms that provide for partial refunds if no eggs are collected, all collected eggs fail to fertilise, treatment does not progress to embryo transfer, or there are no suitable embryos to freeze.
- 7.22 However, we have seen an example where a clinic's terms contained contradictory provisions relating to patients' refunds rights. In particular, the contract appeared to provide for refunds if a treatment cycle was cancelled before egg collection, but this was contradicted by a term purporting to exclude patients' cancellation rights once treatment had started.
- 7.23 As explained in the Guidance, cancellation and refund terms are more likely to be fair where they provide for patients to receive a refund that reflects a genuine pre-estimate of the expected costs savings to the clinic as a result of a cycle not being completed as expected, taking account of the particular services or parts of the service that have not been provided. As also explained in the Guidance, we would expect clinics to provide refunds for add-on treatments or additional services that are purchased in addition to treatment packages, but which do not go ahead. An example of a potentially unfair term relating to refunds would be: "Treatment Services are non-refundable once performed or part performed". This is potentially unfair as it purports to exclude patients' refund rights even where some aspects of the service have not yet been performed.
- 7.24 We have seen some positive examples where clinic terms clearly set out patients' rights to a refund for additional services that are not provided, for example: "Fees for PGD will be refunded where there are no embryos for biopsy". However, most clinic terms did not provide this level of detail in relation to add-ons or additional services purchased on top of a treatment package, instead including only a general indication that partial refunds may be due for services not provided so we were not able to assess the substantive fairness. Such terms may fail to meet the transparency requirement referred to at paragraph 7.13 above. We consider that

<sup>&</sup>lt;sup>140</sup> Paragraphs 5.49 and 5.50 of the CMA's Guidance.

cancellation and refund terms and policies would be improved by greater clarity in this regard.

## Refund terms - multicycle

- 7.25 In relation to multi-cycle packages, we have seen terms which provide for patients to receive refunds on second and third cycles if treatment is cancelled for medical reasons this is in line with our expectations. 141
- 7.26 We have also seen examples of clinic terms providing for patients to cancel a pre-paid multi-cycle package before completion of all the cycles included, and receive a refund consisting of the difference between the price already paid for the multi-cycle package and the price that would have been payable for the number of cycles actually received based on the applicable single-cycle package price. We consider such terms offer patients improved choice and flexibility to decide not to continue with treatment and we welcome the benefits to patients that such terms provide. 142

#### Variation terms

- 7.27 We have seen examples of terms that give clinics unlimited discretion to vary the agreed price to reflect revisions to their general price-list in circumstances where the treatment plan has not changed. For example: "We may review and revise prices at any time without notice." We are concerned that such terms may be unfair as they could be used to force patients who are about to begin, or are going through treatment, to accept higher prices.
- 7.28 As explained in paragraph 5.25 of the Guidance, terms which operate to give clinics a unilateral, unlimited right to increase the price of treatment after the contract has been agreed with the patient, are likely to be unfair under the CRA.
- 7.29 We have also seen examples of terms which provide that prices set out in a personal quotation or costed treatment plan are subject to change at the clinic's discretion. We are concerned that such terms may be unfair, because even if patients agree to proceed with treatment on the basis of the prices given to them, clinics can claim not to be bound by these prices. For example: "We may change our Costs from time to time. We will draw the changes to your attention. Unless we expressly tell you that the Costs will be

<sup>&</sup>lt;sup>141</sup> Paragraph 5.54 of the CMA's guidance

<sup>&</sup>lt;sup>142</sup> There is also less risk of such terms being challenged for unfairness, on the basis of binding consumers to pay for services which have not been supplied.

the Costs set out your Costed Treatment Plan quote, you will pay the Costs which are in effect when you contract with us for Treatment. You will need to check the Costs prior to entering into a contract with us, as they may vary from your Costed Treatment Plan quote."

- 7.30 Under the CCRs, before prospective patients agree to treatment, clinics must provide them with clear price information as part of the required pre-contract information. If clinics want to change the prices set out in a quotation before the patient accepts the offer and proceeds with treatment, the revised price must be expressly agreed between the clinic and the patient (paragraphs 3.59 and 3.60 of the Guidance).
- 7.31 We note that many clinics use terms which provide that prices are only valid for a period of time from the date of a quotation or costed treatment plan. For example: "The prices quoted are valid for a period of 3 months from date of the costed treatment plan." As noted at paragraphs 3.36 and footnote 82 to paragraph 5.25 of the Guidance, we consider that clinics should be able to stipulate that prices quoted in pre-contract information have a time limited validity but they should clearly and prominently set out how long the offer price is valid for. We consider that such terms may nevertheless be unfair if the period of validity is unduly short. Fairness concerns could also arise if, for example, patients are subjected to price increases because they did not start treatment during the stated period of validity where this delay was not at the patient's choice but was because of limited clinic capacity and being held on a waiting list. However, it is our understanding that self-funded treatment ordinarily begins shortly after patients agree to treatment.

#### Time limits

- 7.32 We have seen examples of terms which restrict the time period during which treatment must be taken. For example: "Multi-cycle packages: treatment must be completed within 12 months of first egg collection."
- 7.33 We consider that such terms may be unfair where they set an unreasonable deadline for completing treatment under a multi-cycle package which may be difficult to achieve for some patients. We also consider that such terms require patients to assume a level of risk under the contract that may be unreasonable and imbalanced. Patients may not be in a position to know if the timescale is feasible at the time they buy the package and may be unable to meet the timescales through no fault of their own.

7.34 Therefore, where clinics use terms to restrict the time period during which treatment must be completed, they should ensure that the time-limit is reasonable and does not impose an unfairly high level of risk on their patients. Furthermore, the time limit should be prominently brought to patients' attention before they agree to buy the multi-cycle package, and they should be made aware of the factors that may affect their ability to complete treatment within that timeframe.

# Limitation of liability

- 7.35 We have seen examples of terms that exclude or limit clinics' liability under the contract in a potentially unfair way. For example, we have seen many clinics using terms limiting their liability for loss or damage to an amount equivalent to the price that the patient has paid under the contract. We have also seen terms of this type containing legal jargon or vague wording that may not be understood by patients e.g. "force majeure" and "we may exclude or limit our liability so far as the law permits".
- 7.36 Terms excluding or limiting the amount of compensation that patients can recover if the clinic fails to provide treatment to the requisite standard fall within the scope of paragraph 2 of the list of terms that may be unfair under section 63 and Part 1 of Schedule 2 to the CRA ('the Grey list') and could be open to challenge as unfair. We consider that patients can be harmed by such terms where they are discouraged from exercising their full legal rights when problems occur, or they may not receive the compensation they would otherwise be legally entitled to when things go wrong.
- 7.37 In order to address our concerns, clinics should not exclude or unreasonably limit their liability to patients in their contract terms. Clinics should not seek to restrict a patient's rights under the CRA, and attempts to do so are likely to be unenforceable. Clinics should also avoid using unnecessary legal jargon and should instead clearly explain what the patient's rights against the clinic are in the event that things go wrong, including in any special circumstances where their rights against the clinic might fairly be reduced (see paragraphs 5.63 and 5.64 of the guidance). in our view, terms that simply say liability is excluded to the extent permitted by law are likely to be unclear and uncertain in effect

 $<sup>^{143}</sup>$  See 5.6.1 – 5.6.11 of CMA37 for more information.

and, as such, fail to meet the requirement of transparency and are potentially unfair.

# Assigning the contract

- 7.38 We have seen examples of terms that permit clinics to transfer patients' rights under a contract to a different clinic: "We may at any time assign, transfer, or subcontract any of our obligations under the contract."
- Such terms fall within scope of paragraph 19 of the Grey list under the CRA 7.39 and could be open to challenge as unfair, for example, if the transfer could result in unwanted changes to the patients' treatment. 144 Clinics have no legal right to transfer contracts to other businesses without the agreement of the patient and, given the very personalised nature of the service, we would have fairness concerns with a term purporting to allow them to do so. We have seen examples of clinics' terms undertaking to give patients notice of any assignment and an opportunity to cancel their contract and receive a refund for services not yet provided if they are unhappy with the proposal. However, in our view this might not be sufficient to render a term fair as it would be unlikely to provide a satisfactory remedy for patients who were in the middle of treatment and who objected to the change. Furthermore, we have seen terms where in our view the time given to patients to object to the proposed assignment of their contract was not reasonably sufficient to ensure they would have seen the notification and had time to consider how to respond. This is another factor which could make the term unfair. These types of terms are more likely to be fair if they only apply where (i) the patient agrees to the assignment, or (in the absence of the patient's agreement) (ii) the patient's treatment hasn't started and a full refund would be given.

# Improvements to terms and conditions

- 7.40 As explained at paragraph 7.8 above, we wrote to some of the sample clinics we reviewed in detail to highlight specific concerns we had identified with the terms that they used with their patients. We told the clinics that we expected them to review their terms and make appropriate changes to ensure their compliance with consumer law.
- 7.41 Most of the clinics we contacted have subsequently made changes to address concerns we identified with their terms We welcome the constructive approach adopted by clinics. We are continuing to engage with some of the

<sup>&</sup>lt;sup>144</sup> See paragraphs 5.28.1 – 5.28.4 of CMA37 for more information.

clinics to resolve a small number of outstanding issues. Examples of the types of changes include:

- Creation of a contract for patients (where one did not previously exist).
- Improved consistency in how rights and obligations are described where they are contained in multiple documents.
- Terms being amended to better reflect patients' statutory rights under consumer law.
- The removal of a cancellation term which permitted a clinic to retain full prepayments in circumstances where the patient receives no services.
- Amendments to time limit terms to explain that extensions to the period during which treatment must be taken will be allowed for clinical reasons and personal preference on a case-by case basis.

#### Recommendations

- 7.42 We strongly recommend that clinics review their terms in light of the compliance concerns identified in this chapter and take any corrective action necessary as a matter of priority. Clinics should not assume that because we have not written to them directly to highlight concerns, their practices are compliant with consumer law. Failure to comply with consumer law could result in the CMA, or others, taking enforcement action.<sup>145</sup>
- 7.43 We also recommend that clinics ensure that their terms can be easily located by and are accessible to prospective patients, and that such terms are brought to patients' attention in a timely manner before they agree to any treatment.

<sup>&</sup>lt;sup>145</sup> See CMA Guidance, paragraph 1.26,

# 8. Complaints

#### Introduction

- 8.1 Unlike the other issues described in chapters 4 7 above, we had not been alerted to any particular compliance concerns in relation to complaints handling when we produced the Guidance. We had however been told anecdotally by some stakeholders that patients can be reluctant to complain.
- 8.2 Drawing on our 2022 patient research, this chapter begins by exploring why patients might be reluctant to complain. It then explains in brief how consumer law applies, before summarising the findings from this part of the compliance review. The chapter concludes with a recommendation to the HFEA to consider how it can encourage subscription to a voluntary ADR scheme and a recommendation to clinics that they review their own information and practices in light of the compliance concerns highlighted in this report.

## Why might patients be reluctant to complain?

- 8.3 Many patients, including those whose treatment has been unsuccessful, are satisfied with their clinic. 146 But there are also times when patients are dissatisfied. The CMA has heard from stakeholders who work with patients that patients can feel uncomfortable about raising concerns or complaints with their clinic, especially if their treatment is underway.
- 8.4 Our 2022 patient research found that for a number of reasons, patients typically felt that raising a complaint about fertility treatment was different to raising a complaint about other products or services that they had bought. It also found that patients were in a unique frame of mind as consumers that drastically differed from how they feel as consumers of other products or services. This meant that when issues arose or when things went wrong, the ways patients chose to interact with their clinics did not always align with how they might have acted if they were consumers in another sector. Ultimately this meant that the decision about whether or not to complain was less straightforward. On top of this, for many patients, purchasing fertility treatment tended to be a uniquely private experience and they felt that there was no understood 'norm' in relation to how someone should be treated or what they should reasonably expect from a clinic. 147

<sup>&</sup>lt;sup>146</sup> The HFEA's National Patient Survey 2021 found that 71% patients were satisfied with their latest experience of fertility treatment.

<sup>&</sup>lt;sup>147</sup> CMA's 2022 patient research (section 6.2, pages 55)

8.5 Most of the research participants reported having an issue, of varying degrees of importance, with their clinic. <sup>148</sup> Of these, just over half said that they did not raise this with their clinic for a variety of reasons. These included not considering the issue significant enough to complain about; not wanting to add stress to an already emotional purchase; not wanting to upset the relationship with their clinic; not wanting to jeopardise their treatment; or because the treatment had been successful or the patient had 'moved on'.

'Some things [in the IVF process] you have to swallow and accept it because it's not worth the stress.' [36, Midlands, Private clinic]<sup>149</sup>

'I needed them more than they needed me, and I couldn't be without them, so I'd have rather had a bad service than no service.' [31, Midlands, NHS clinic]<sup>150</sup>

'I was emotionally not in the right place to make a complaint. I didn't want to do a formal complaint; I would've just sent an email to see if it was a pattern of behaviour. But for the next month or so I wasn't in the place to do it, and then I had moved on.' [40, South, Private clinic] 151

## When patients were satisfied with complaint handling

8.6 Our 2022 patient research found that of those that did make a complaint, the majority of these (13/15) felt satisfied with the result. This is because they reported clinics responding immediately to their concerns and offering apologies. For those who continued to have further treatment at the same clinic, satisfaction came from how future engagement with the clinic differed, proving that they had taken the feedback on board 152.

"We knew the treatment had failed four days after because I started bleeding. They brushed it off and said bleeding was normal so I said to them you should take it more seriously; I knew my progesterone level was too low. They laid out what would they do next time to make sure these issues wouldn't repeat themselves. So, for the next cycle they tested my progesterone two weeks before transfer and gave me daily injections. So, they completely responded to my concerns. I liked that

<sup>&</sup>lt;sup>148</sup> Around two-thirds of patients (31/44) that participated in the CMA's 2022 patient research reported experiencing an issue but only around half of those (15/31) raised the issue with the clinic - CMA 2022 research (section 6.4, page 57-60)

<sup>&</sup>lt;sup>149</sup> CMA 2022 research (section 6.4, page 59)

<sup>&</sup>lt;sup>150</sup> CMA 2022 research (section 6.4, page 59)

<sup>&</sup>lt;sup>151</sup> CMA 2022 research (section 6.4, page 59)

<sup>&</sup>lt;sup>152</sup> CMA 2022 research (section 6.5, page 61-62)

they do listen to me and adapted it and recognised that I know my body and know what I'm talking about."

- 31, North, Private clinic

# How consumer law applies to complaints

- 8.7 Chapter 6 of the Guidance explained that to help them comply with consumer law, clinics should ensure that their complaints handling policies are easy to locate, accessible, clear and fair to patients. It also set out that clinics:
  - Should tell patients how they can escalate their concerns or complaints if they are dissatisfied with how the clinic has handled their complaint.<sup>153</sup>
  - Risk infringing consumer law if their policies, practices or terms have the
    effect of discouraging someone from making a complaint or from
    escalating it if they are unhappy with how it has been dealt with.<sup>154</sup>

# **HFEA** and complaints

- 8.8 The HFE Act requires licensed clinics to have, and adhere to, a complaints procedure. Complaint handling is covered in the HFEA's code of practice. 155
- 8.9 The HFEA also provides advice to patients on their website about making complaints about clinics. This includes information about the HFEA's role in patients' complaints. The HFEA can consider complaints made by patients or donors about licensed clinics where these indicate a breach of the clinic's licence conditions, the HFE Act or the HFEA's Code of Practice or directions it issues to licensed clinics, and where the patient has exhausted the clinics' complaint process. Such complaints may result in the HFEA sharing learning points with the clinic concerned and, if appropriate, with all licensed clinics. Where the complaint indicates a compliance failure by the clinic, the matter may be brought to the attention of the HFEA's Licence Committee.
- 8.10 The HFEA explain that by law they are only able to deal with certain complaints. They cannot review specific decisions about patients' clinical care, nor can they help patients obtain a refund or compensation. 157

<sup>&</sup>lt;sup>153</sup> Paragraph 6.5 of the CMA's guidance on consumer law

<sup>&</sup>lt;sup>154</sup> Paragraph 6.2 of the CMA's guidance on consumer law

<sup>&</sup>lt;sup>155</sup> Chapter 28 of the HFEA's code of practice - Read the Code of Practice | HFEA

<sup>156</sup> www.hfea.gov.uk/choose-a-clinic/problems-at-the-clinic

<sup>157</sup> www.hfea.gov.uk/complaints policy

## **Compliance Review Activities**

8.11 Our compliance review looked at whether clinics had complaints handling policies, whether information about those policies was easy to find, whether they were easy to understand and use, and the options available to patients to escalate if they were dissatisfied with the clinic's handling of, or response to, their complaint. We assessed complaints handling policies provided directly to us by some clinics in response to a request for information. We also looked at whether information about complaints handling procedures was available on clinic websites.

# **Compliance review findings**

- 8.12 The main findings from our review of complaints handling information are:
  - Most of the complaints handling policies we looked at clearly set out where and how complaints can be made, and the timescales for responding to the complaint.
  - Some clinics have wording in their complaints handling policies that has the potential to mislead patients about their options for escalating complaints.
  - Few HFEA licensed clinics have subscribed to a voluntary ADR scheme for the private healthcare sector and as such most patients paying for their fertility treatment are not able to access an ADR scheme.

#### Compliance with consumer law

- 8.13 We found that some clinics have standalone complaint handling policies available from their websites<sup>158</sup> or that are made available in clinics. Some clinics also provide details of their complaint handling policies in their contract terms, costed treatment plans, and other information given to patients.
- 8.14 We have seen some positive examples of some clinics' complaint handling policies that are easily located and visible to patients (for example, available on clinic websites), and which clearly set out where and how complaints can be made, the timescales for considering complaints, and which detail how complaints can be escalated.

<sup>&</sup>lt;sup>158</sup> Often available from hyperlinks on the bottom of clinics' landing or home webpages or dedicated 'patient resources' webpages

#### Concerns

- We have seen examples of potential non-compliance with consumer law, where some clinics have wording in their complaints handling policies that have the potential to mislead patients. For example, some policies, as illustrated below, may mislead patients about their options for escalating complaints by mispresenting the HFEA's role in considering complaints and/ or suggesting that the patient can escalate complaints to an independent third-party complaints adjudication scheme whose service the clinic does not subscribe to.
  - 'If you are not satisfied with our response, you may wish to contact the HFEA in England or the Health Inspectorate in Wales. These authorities act as an "Alternative Dispute Resolution" service" and may be able to consider your complaint.'
  - 'If you are not happy with our response, you then have the further option of contacting the HFEA to determine whether they are able to look further into your concerns or the Independent Sector Complaints Adjudication Service.'

# Alternative Dispute Resolution

- 8.16 There is currently no mandatory Alternative Dispute Resolution ('ADR') scheme that patients paying for their treatment can escalate complaints to if they are dissatisfied with clinics' responses to their complaints. This contrasts with patients who have had their fertility treatment funded by the NHS as they can access an ADR scheme by submitting complaints to the Parliamentary and Health Service Ombudsman (PHSO) in England, the Public Service Ombudsman in Wales (PSOW), the Scottish Public Services Ombudsman (SPSO) or the Northern Ireland Public Services Ombudsman (NIPSO). 160
- 8.17 We are currently aware of one voluntary ADR scheme in the private healthcare sector. This is the Independent Sector Complaints Adjudication Service (ISCAS). 161 Our review found that membership of ISCAS by HFEA licensed clinics is currently extremely low. 162 By contrast, we note that

<sup>&</sup>lt;sup>159</sup> In this case, the clinic did not subscribe to this adjudication service, so escalation to this body was not in fact an option for the patient.

<sup>&</sup>lt;sup>160</sup> www.ombudsman.org.uk - Wales/nhs complaints - Northern Ireland/complaints about NHS - Scotland feedback and complaints and www.ombudsman.org.uk/private-healthcare These Ombudsmen cannot accept complaints from private patients.

<sup>&</sup>lt;sup>161</sup>https://iscas.cedr.com/about/what-we-do/

<sup>&</sup>lt;sup>162</sup> Most of the few that do subscribe are part of healthcare providers that are providing a wide range of private healthcare services, not just fertility treatment.

- membership by private healthcare providers, regulated by the Care Quality Commission (CQC), is currently extremely high. 163 The CQC works with ISCAS, for example they have information sharing arrangements in place. 164
- 8.18 We are aware that in other regulated sectors businesses are required to belong to a mandatory ADR scheme or are encouraged to sign up to a voluntary ADR scheme. 165 We are also aware of the recommendation from the Paterson Inquiry 166 that all private healthcare patients should have the right to mandatory ADR. In its response, the Government accepted this recommendation in principle. The CMA has drawn to the DHSC's attention that it appears that self-funded fertility patients have been overlooked as the response refers to healthcare providers regulated by the CQC and that, in its view, self-funded fertility patients should form part of any consideration that ADR be made mandatory for private healthcare patients.
- 8.19 We are concerned that most patients paying for their fertility treatment are not able to access an ADR scheme. Especially so, given that all patients who have fertility treatment funded by the NHS, and most patients paying for other types of private healthcare, can access an ADR scheme. This is also out of line with the experience of consumers in other regulated sectors. We are not aware of any objective justification for maintaining this unequal position.

#### Recommendations:

- 8.20 We recommend the HFEA encourages all licensed clinics to join an independent ADR scheme, in a similar way as the CQC does. We further recommend that the HFEA considers whether membership of an ADR scheme could be incorporated into their Code of Practice.
- 8.21 We recommend that clinics review the information they provide to patients on how to make a complaint to ensure that they do not mislead patients about the routes available to them to escalate complaints.

<sup>&</sup>lt;sup>163</sup> The CQC,regulates health and adult social care in England, including private healthcare. The DHSC has advised the CMA that around 97% of the CQC regulated private healthcare sector subscribe to ISCAS.

<sup>&</sup>lt;sup>164</sup> https://www.cqc.org.uk/guidance-providers/independent-healthcare/how-we-work-national-partners-independent-healthcare

<sup>&</sup>lt;sup>165</sup> For example, the FCA, OFGEM, OFCOM, the Gambling Commission, CAA and OFWAT.

<sup>&</sup>lt;sup>166</sup> Published on 16 December 2021 (Government response to the Paterson inquiry)

# 9. Summary of recommendation and next steps

- 9.1 Throughout the report we have made a number of recommendations aimed at clinics and at the HFEA. These are summarised in paragraphs 9.3 9.9 below along with wider recommendations for the sector.
- 9.2 We also summarise in paragraphs 9.10-9.14 our next steps to promote improved and continued compliance with consumer law in the sector.

#### 9.3 Recommendations for clinics:

- We strongly recommend that all clinics read this Findings Report and review their information, practices and contract terms in the light of the various examples of potential non-compliance that we highlight. Clinics should also ensure that their information and commercial practices during the parts of the patient journey that we have not been able to assess are compliant with consumer law. They should read our Guidance alongside this Report, and take any corrective action necessary, as a matter of priority.
- Clinics should make sure that all patient-facing staff, including clinical staff and those involved in producing patient-facing materials understand the consumer law requirements and comply with them.
- Clinics should not assume because we have not written to them directly, that their practices are compliant with consumer law. Failure to comply with consumer law could result in the CMA, or others, taking enforcement action.
- We recommend that clinics and other key stakeholders work with the CMA
  to explore the feasibility of developing a standard approach for what is
  included in the headline price for a single cycle package of IVF. To be
  clear this is about the presentation of price information to help patients
  meaningfully compare clinics' prices. It is not about the prices clinics
  charge or any form of price regulation.

#### 9.4 Recommendations for the wider fertility sector:

- We recommend that other businesses active in the fertility sector consider how the Guidance, consumer law requirements, and the findings in this report apply to them. Failure to comply with consumer law could result in the CMA, or others, taking enforcement action.
- 9.5 Recommendations for patients and patient representatives:

 We encourage patients and patient representatives to read and consider the CMA's guide for patients<sup>167</sup> on their consumer rights when buying fertility treatment. Patients may bring legal proceedings for a clinic's breach of contract or seek redress in the courts for certain breaches of consumer law.

#### 9.6 Recommendations for the HFEA:

- We recommend that the HFEA makes reviewing costed treatment plans an inspection priority, to ensure that clinics provide all patients with a costed treatment plan that includes all the information set out in HFEA's code.
- We recommend the HFEA encourages all licensed clinics to join an independent ADR scheme, as the CQC does. We further recommend that the HFEA considers whether membership of an ADR scheme could be incorporated into their Code of Practice.

# 9.7 Wider Policy Initiatives

We will respond to the HFEA's consultation on legislative reform. We
consider the HFEA's current toolkit is not sufficiently flexible, particularly
given that this is a commercialised and competitive sector. We agree with
the HFEA that a wider range of directly enforceable sanctions, such as
financial penalties, should be considered. Such sanctions are likely to be
helpful for targeting clinic practices which can harm the financial interests
of fertility patients, such as those outlined in this report.

#### Next steps

- 9.8 To help further raise awareness of consumer law obligations and to promote compliance, we are sharing this findings report with:
  - other sector regulators such as the HFEA, CQC and the GMC
  - relevant professional bodies such as the BFS, ARCS, SING, BICA and RCN
  - patient representative organisations

<sup>&</sup>lt;sup>167</sup> Fertility treatment: A guide to your consumer rights - GOV.UK (www.gov.uk)

- the DHSC
- our enforcement partners such as trading standards service
- 9.9 We will also be writing to some overseas based clinics that advertise their services to UK consumers to make them aware of their obligations under UK consumer law.
- 9.10 We plan to hold roundtable discussions with clinics and other key stakeholders in Autumn 2022 to explore the feasibility of developing a standard approach for what is included in the headline price for a package for a single cycle of IVF, as well as a consistent approach to providing price information for any key aspects of treatment not included in the standard package for a cycle.
- 9.11 Finally, we are continuing to engage with some clinics about a small number of outstanding non-compliance concerns we have brought to their attention. We expect all clinics to comply with consumer law. Failure to comply with consumer law could result in the CMA, or others, considering taking enforcement action.