HFEA LICENCING COMMITTEE

APPPLICATION OF HFEA AND MR TARANISSI

Determination

1. This hearing concerns the application by the HFEA to impose condition 123 upon the licences of the two centres run by Mr Mohammed Taranissi which are numbered 0157 and titled the Assisted Reproduction and Gynaecology Centre (ARGC) situated at 13, Upper Wimpole Street, London W1G 6LP and 0206 and titled the Reproductive Genetic Institute (RGI) 32A Weymouth Street, London W1G 7BX.

2. The hearing has unfortunately been held over a more extensive period than we would have preferred. So far as this committee is concerned the first hearing was on 3 December 2012 (which had to be adjourned because of illness) and the second was on 10 December 2012. The third and final hearing took place on 18 March 2013 and on this occasion Ms Gallafent (counsel) had replaced Catherine Callaghan (counsel) for the HFEA and we heard the final submissions of Ms Richards QC on behalf of the Centres.

3. We were assisted by written submissions from both sides and before this hearing we have taken the opportunity of refreshing our memories from the previous transcripts and reviewing the documentation.

4. We are grateful for the legal advice given by the legal assessor and for the assistance given as to the background to this application and the relevant law which we must apply and from which neither party demurred and we have taken that fully into account. Although Mr Kark QC summarised the arguments and commented upon them we fully take on board that what we make of the arguments is a matter for us. In so far as the legal assessor made any comment upon the facts or arguments during the course of his advice in the hearing we have only taken account of those comments with which we ourselves independently agreed.

5. In coming to our decision we have borne in mind the following principles:

    i) We are an independent panel and have applied our objective judgment to the issues which have been raised;

    ii) We have only taken into account that which has been put before us in these hearings and have ignored external material;

    iii) We have been reminded of our obligation not to indulge in speculation and to focus upon the arguments and evidence before us;

iv) We have borne in mind throughout that it is for the HFEA to persuade us that it is appropriate to impose this condition and that there is no burden upon the centres to persuade us that we should not;

v) In relation to the standard of proof which we apply in relation to issues of disputed facts we have borne in mind that the standard we apply is the civil standard meaning that before we accept a fact we have to take the view that is it more likely to be true than not.

vi) The HFEA had to demonstrate that any condition which they seek to impose must accord with best regulatory practice principles. It was for the HFEA therefore to demonstrate to us that the imposition of this condition would be: transparent; accountable; proportionate; consistent; and targeted.

THE HISTORY

6. We are grateful for the explanation summarised by the legal assessor of the historical background leading to the imposition of this condition 123 which was the issue before this committee. It was as follows and the exhibit page references (xp.) are to the page numbers in the main hearing bundle. Tab numbers also refer to the tabs in the main hearing bundle.

7. In October 2006 Professor Peter Braude produced the report of an expert group set up to consider multiple births. The report is at xp.4 and they found strong evidence to demonstrate significant potential problems both for the mothers and the babies involved in multiple births.

8. His group concluded that the only way to reduce multiple births was to transfer one embryo at a time to those women most at risk of having twins. Overall he said Elective Single Embryo Transer (eSET) should be the norm.

9. This was followed by a consensus statement on 3 April 2007 by 8 professional organisations and 11 patient organisations. Xp.10.

10. The consensus statement was to the effect that multiple births were the single biggest risk to the health and welfare of children born after IVF, (conclusion at xp.15). Also in April 2007 the HFEA issued a consultation document on the same issue (xp.16).

11. On 7 May 2008 the HFEA met to consider the latest information on the policy regarding multiple births (xp.54) and following this the first direction in relation to the implementation of a policy to reduce multiple births was introduced from 1 January 2009 and the maximum multiple birth rate per centre per annum was set at 24%.

12. The committee was told that before the licence condition which we have been asked to consider was introduced, the regulatory approach driving the multiple births policy involved general directions issued under the Act. General directions were issued to centres in each year of the policy, which specified the maximum multiple birth rate and required centres to

maintain a record of their own multiple births minimisation strategy. They were also required to audit the effectiveness of their own strategy. Centres were required to come up with their own strategy setting out how they planned to reduce their maximum multiple birth rates. Beyond these types of directions there was no more concrete element to the enforcement of the policy.

13. On 1st October 2009 a compliance and enforcement policy was issued (xp.63) which was in accordance with the recommendations of the compliance committee made on 2/9/09 and which stated that – as from October 2009 the authority had a specific statutory duty to promote compliance with the requirements both of the Act and the Code of Practice issued by it under S25 of the Act.

14. On 20 January 2010 the HFEA issued its Multiple Birth Year 2 target and enforcement policy. Xp.80. The year two multiple birth maximum target ran from 1 April 2010 to 31 March 2011 and was set at 20%.

15. On 19.11.10 The Multiple Births Stakeholders Group Meeting strongly recommended that the authority set a Year 3 maximum multiple birth rate of 15% (See TAB 15 para 3.3) and that that should be imposed as licence condition.

16. On 8 December 2010 a paper (TAB 15) was produced by Helen Richens, Policy Manager at the HFEA setting out a series of recommendations in relation to the HFEA's commitment to reducing multiple births. It set out a brief history of the success of the policy introduced in January 2009 and asked members of the Board to agree a recommendation for a maximum birth rate for the third year of the policy and that that should be imposed as condition on all licences (TAB 15 para 3.16, 3.21).

17. The advantages of imposing the strategy as a condition upon licences were set out in the December 2010 paper at para 3.18 (TAB 15)

    i) That a licence condition around multiple births was a visible signal to the sector that the HFEA 'takes the policy seriously and will be prepared to act against centres who continually fail to comply'

    ii) A licence condition adds legal enforcement to the policy and provides inspectors with a concrete requirement against which they can inspect. If a centre does not comply there are a series of escalating steps which can be taken.

18. On the same date 8 December 2010 that paper was considered by the HFEA (TAB 16 See para 7).

19. The decision of that committee was to follow the recommendations made by Helen Richens (See TAB 16 para 7.17).

    i) That the max multiple birth rate should be set at 15%;

ii) That the directions be updated so that the new rate came into force in April 2011;

iii) Para 7.1 of the code of practice be accordingly updated as of April 2011;

iv) Guidance should be issued in the Code of Practice around double blastocyst transfers.

20. On 10 January 2011 a direction under S24 of the Act was issued by the HFEA which came into force on 6 April 2011 but this policy was still not enforced by a formal condition.

21. The directions were to the following effect –

    The first section dealt with issues of recording information on the number of eggs and embryos transferred;

    The second section was headed – 'Multiple Births Minimisation Strategy'

    Para 3 required centres to maintain a documentary record of their Multiple Birth Minimisation strategy

    Para 4 sets out the form of the strategy which includes - a section identifying how the centre intends to reduce its annual multiple birth rate and to ensure that it does not exceed the maximum rate of 15% of the annual birth rate for the centre.

22. This therefore followed the previous policy of requiring a strategy to be developed but not going so far as to impose a specific condition limiting multiple births. The history to date therefore of the progression of the limitation upon the multiple birth rate as set out in the directions was:

    In Year 1 (1 January 2009 to 31 March 2010), the maximum multiple birth rate had been set at 24%;
    In Year 2 (1 April 2010 to 31 March 2011), the maximum multiple birth rate was set at 20%;
    In Year 3 (6 April 2011 to 30 September 2012), the maximum multiple birth rate was set at 15%.

23. The April 2011 direction meant that each centre should produce a strategy to ensure that it did not exceed a rate 15% of multiple births out of its total annual birth rate. Para 7 required the centre to record where multiple embryos have been transferred to a patient who met the criteria for single embryo transfer as set out in the strategy together with a clear explanation for the reasons for doing so in that particular case and a note confirming that the risks of multiple pregnancy have been explained to the patient. Short of imposing a condition upon a licence we were told that the type of directions which the HFEA could introduce were curtailed by Statute and that this direction was as far as the authority could go in seeking to impose its policy.

24. However, on the 19 May 2011 the Executive Licensing Panel, an authorised body under the HFEA and delegated with this task by the Chair of the Authority and by the Chairs of the

Licensing and Research Committees decided upon advice that it was appropriate to alter a number of the licence conditions as well as insert a new licence condition for all treatment and storage licences (TAB 4 & 5). It was empowered to take such action by S18A(5) of the HF&E Act 1990, which is a wide provision and gives the authority a general discretion to vary licences by adding conditions.

25. One of those new licence conditions was intended to enforce the multiple births policy and ensure that such licensed organisations reduced the number of multiple births which occurred as a result of the insertion into a woman of a number of embryos. The preferred course, on the basis of medical research was that single embryos should be inserted where possible. However, consistent with the previous policy, the licence condition was not targeted at the number of embryos inserted, it was targeted at the outcome of that procedure.

26. The condition which the HFEA imposed throughout the sector was condition 123 which states –

"The centre must not exceed the maximum multiple birth rate specified by directions".

27. As previously stated the directions imposed a maximum limit per annum on the number of multiple births per licensed centre. This is the condition to which Mr Taranissi and his centres object. The directions specified that the maximum multiple birth rate for year 4 (1 October 2012 onwards) should be 10%.

The Principal Issues

28. The principal issues surrounding the imposition of the condition appeared to us to be the following :

i) The HFEA argue that there is a public interest in seeking to reduce the multiple birth rate because research shows that multiple births significantly increase the risk of adverse events both for the mother and the foetus or child. Those adverse events include premature birth, respiratory distress syndrome, cerebral palsy and other developmental problems lasting many years. There are also significant potential adverse effects upon the mother including pre-eclampsia and gestational diabetes. We accept this evidence which has not been challenged. There was indeed no challenge to the appropriateness of the multiple births policy or strategy but the issue is whether or not a condition should be imposed to enforce it

ii) The natural multiple birth rate is between 1 and 2% and so, the HFEA submits, there is already considerable latitude being offered in the reduction to 10% by fertility clinics, ie: five times the national average. It is not envisaged, say the HFEA, that that rate will be further reduced. We accept the figures given which again have not been challenged but we have not proceeded on the basis that there may not be a further reduction in the future.

iii) The multiple birth rate is directly linked to the practice of inserting more than one embryo into a woman. This again has not been challenged and we accept this analysis in principle.

iv) By offering Single Embryo Transfer (SET) to around 50% of patients the HFEA argued that the centres would be able to stay within the 10% multiple birth maximum. It was submitted on behalf of the centres that there was a lack of evidence to support this proposition. Although there was limited evidence to support the proposition we took account of the data provided in the document produced at xp.248 – the Authority paper on the Multiple Birth year 3 target. This provided a scientific basis for demonstrating that overall pregnancy rates for DET and SET were not vastly different although DET had a slightly higher pregnancy rate as the patient got older. SET almost eliminates the danger of multiple births. We therefore accept the contention that it is only necessary to ensure no more than 50% of patients receive DET to ensure that the 10% target is met provided the patients are carefully selected for receipt of two embryos. However, whether this is correct or not, we did not think this was a critical or determinative issue.

v) The HFEA argue that imposing a licence condition is a natural extension of their pre-existing policy to reduce multiple births. This is not a 'bolt out of the blue' they say and anyone within the industry should have been preparing for it, it has been well trailed and signalled in advance. The centres argue that there was no warning of this move and it was not properly trailed nor consulted upon. Although there appears to have been little or no warning that a condition might be imposed the policy of reducing the multiple birth rate has been very clear and public since 2007. We gave consideration to the issue of public consultation and although there appears to have been consultation in relation to the policy generally we could find no evidence that there had been consultation in relation to the imposition of the condition itself. We found however that there was no statutory requirement for consultation to take place prior to the imposition of a new condition and this condition was plainly in line and consistent with the publicly stated policy of the authority. Furthermore it was specifically targeted at a recognised medical issue.

vi) The HFEA argue that imposing a condition is now reasonable and proportionate – because although the industry has shown its ability to behave responsibly and comply with directions in the past, the new maximum of 10% multiple births will be

harder to meet and so is unlikely to be adhered to without a condition being imposed. This was challenged by the centres who argued that this was not a reasonable and proportionate step given that the industry had demonstrated its willingness to comply voluntarily with previous maximum rates published as guidance. There was, they said, no evidence that they would not comply and therefore imposing a condition was not reasonable. We found that although the sector had responded when the rate was previously reduced, the reduction now aimed at was, as the HFEA said, very challenging, and we accept that it would be unlikely to be met by merely using the guidance or directions. We also noted the dichotomy that whilst relying upon the sector's overall compliance with the directions to bolster the argument that a condition was unnecessary Mr Taranissi's centres appeared to have less inclination to comply with the overall policy based upon their different patient cohort, thus this application.

vii) The HFEA argue that unless a condition is imposed upon all licenses then the industry will not be competing on a level playing field. The centres argued that the committee should take account of the fact that these centres attracted a different patient cohort and therefore would be disadvantaged by comparison to other centres offering similar treatment. This argument is dealt with in more detail below.

viii) The centres argue that to impose a condition of this nature would deny individual patient choice and proper clinical discretion. It was argued that doctors were required to do the best for the patient in front of them and that meant that if the patient's best chance of becoming pregnant was the insertion of two embryos, then whether or not that raised the risk of multiple births the clinician was bound to advise the patient that that was the appropriate procedure. The HFEA argued that they were not seeking to ban all multiple embryo transfers, nor all multiple births. There would still, they said, be appropriate clinical choice within the overall cap of 10% multiple births. We took the view that although there were circumstances where this policy might have implications for patient choice the duty of the clinician in these circumstances was not simply to consider what was the best chance of ensuring the patient's treatment by IVF was successful. The clinician had a duty to consider more widely the potential dangers to the patient, to the foetus and to the infant which the danger of multiple birth presented. The condition was specifically not aimed at preventing two embryo transfers in every case but was aimed at

reducing the number of potentially dangerous multiple births as a result. Thus we were of the view that the appropriate level of clinical autonomy and patient choice would be preserved in appropriate cases.

ix) The HFEA say that the condition does not require SET in every case. Particularly for older women it may be that DET is suitable provided the centre ensures it is able to keep to the condition if imposed. Indeed the HFEA emphasises that for older women DET may be entirely appropriate given the lower likelihood of multiple births.

x) The HFEA argued that the licence condition provides inspectors with a concrete requirement against which they can inspect and test compliance and that breach will bring into play not automatic revocation of a licence but a series of escalating steps to bring the centre into line with the stated policy. We accepted that the policy of the HFEA was to apply an escalation procedure but were not convinced that in certain circumstances this power of escalation might not be used very rapidly. We accept that it is the duty of the HFEA to enforce its conditions and provided they do so in a matter consistent with their policy and guidelines, how precisely they do that is not a matter for this committee.

xi) Central to the arguments put forward on behalf of the centres was the suggestion that they had a particular patient cohort which, if not unique, was unusual and which set them apart from other centres in the same sector. It was said that the imposition of this condition would therefore have a disproportionate effect upon these centres. The two particular cohorts of patients were those older patients (meaning over 40) who found it harder to conceive by IVF and secondly those under forty who had previously failed to conceive despite the assistance of fertility treatment at other centres. ARG, we were told, sees double the number of women in the 40-42 age group and under half those in the 35 bracket. Having considered these arguments carefully we did not find them persuasive for the following reasons:

a) In relation to the patients who were over forty we received evidence (see xp.115) which was unchallenged and which we accepted that the likelihood of them conceiving multiple foetuses was much lower than for those under forty. It followed that the likelihood of multiple births from this patient group was therefore relatively low. This was so whether or not dual embryo transfer was used. We therefore

came to the view that whether or not this was a specific patient cohort of the centres, the imposition of the condition which focused not upon the procedure used (whether ESET or DET) but upon the outcome of multiple births would not significantly disadvantage these centres in relation to this patient group;

b) In relation to the younger patients who had failed elsewhere to conceive through IVF we again considered the arguments put forward on behalf of the centres but came to the view that unless the centres were simply ignoring the HFEA directives in relation to multiple births then it could not be that their only strategy was to use DET far more frequently. If DET was being used far more frequently at Mr Taranissi's centres then this would mean that the clinicians concerned were more willing than elsewhere to risk the complications which multiple births might bring following DET. The alternative was that, as Ms Richards by implication contended, the clinicians at the centres were simply better than at other centres. If it were the former and DET was being used more frequently at these centres than at others in the sector and a greater risk was therefore being taken, many more women were going to be drawn to those high success clinics, and unless the condition is imposed there would be nothing to stop those clinics continuing to take the risk. That would be a good argument to impose the condition. If it were the latter and the techniques used at the centres were more effective than elsewhere and this success was not simply the result of a greater use of DET than elsewhere then the risk of multiple births ought to be no higher.

xii) It was also submitted that the HFEA has imposed this condition without any idea of the likely effect on the birth rates. It was claimed by the HFEA that the pregnancy rate was 'holding up' and we were told that if anything the trend was upwards. There was a lack of evidence about this issue but in our view it is not a critical issue for us to decide. The policy of the HFEA is to reduce multiple births because of the inherent dangers therein. That may or may not have an undesirable effect upon the total birth rate as a result of IVF. The appropriateness of that policy is not challenged by the centres and so whether it is enforced by direction or condition if successful it will have the same effect averted to on the overall birth rate.

Conclusion

29. Having listened to and weighed all of the arguments including but not limited to those outlined above, we are persuaded that the proposed condition and the policy of the HFEA in imposing it is reasonable as well as being transparent; accountable; proportionate; consistent; and targeted. Further we are of the view that the HFEA has discharged the burden upon it and has established that it is necessary and appropriate that condition 123 should be imposed upon the licences of the two centres under consideration.