British Fertility Society

response to the

Department of Health

public consultation on

Public consultation on Human Fertilisation and Embryology Act 1990 (amendment) regulations 2006, to transpose Directive 2004/23/EC and supporting Commission Directives into UK legislation

October 2006

This document represents the British Fertility Society (BFS) response to the Department of Health's Public Consultation on the Human Fertilisation and Embryology Act 1990 (amendment) regulations 2006, to transpose Directive 2004/23/EC and supporting Commission Directives into UK legislation.

The British Fertility Society is a multi-disciplinary organization representing professionals with an interest in reproductive medicine. The objectives of the society are:

- To promote high quality practice in the provision of fertility treatment.
- To provide a common forum for members of various disciplines having an interest in the science and treatment of infertility.
- To promote high quality scientific and clinical research in the causes and treatment of infertility.
- To provide professional leadership in the provision and regulation of infertility services.
- To promote the increase of NHS funding for and equity of access to fertility treatments.

The provision of assisted conception is an important part of the workload of BFS members and as such the society has an interest in policy developments in this area.

To respond to this consultation, BFS membership were circulated by email and asked to send in their replies using the standard proforma. This response represents the majority view of those who replied and was compiled by Mark Hamilton on behalf of the Executive Committee.

It is submitted by the Honorary Secretary whose contact details are:

Dr. Allan Pacey
c/o British Fertility Society Secretariat
22 Apex Court
Woodlands
Bradley Stoke
BS32 4JT

bfs@bioscientifica.com

Regulations

1. Are any amendments to the Regulations required? If so, please give specific amendments.

Part 2: Requirements of the Directive

Article 2: *BFS notes the extension of treatments and procedures covered by the new legislation.*

For Surgical Sperm Retrieval centres carrying out such procedures in general hospital operating theatres may face considerable additional administrative workload to bring the theatre hierarchy in to their organisational chart.
It is not clear as to whether Internet based sperm providers will fall under the terms "processing" Line 4 Page 11 since in some instances these organisations merely act as so-called introduction agencies between donors and recipients.

Article 8: *The inconsistency of time scale for retaining information for traceability purposes between HFEA and the Directive (50 years vs 30 years) merits examination.*

Article 9: *Standardisation across the 25 EU states for monitoring import and export of gametes will be a difficult task.*

Article 12: ***"****Member states should endeavour to ensure voluntary and unpaid donation". It is interesting that this is not a legal requirement as current in UK practice. The question of protection of anonymity of donors is avoided. Is there a reason for this apparent inconsistency?*

Article 16: *The expense of introducing a Quality Management System (QMS) is an important concern for clinics in the UK. Inevitably the burden for underwriting this additional cost will be on patients. In the state sector this will impact on the number of treatment cycles funded in the NHS.*

Article 17: *It is not a requirement of the Directive that the regulatory authority approves the appointment of the Responsible Person. Why has this been included in the UK revision?*

Technical Annex 1 (Page 15)

Article 4: *The wording in this section (p15) suggests that, if the sexual partner of a donor is deemed to be at high risk of infectious disease, he/she should be screened in addition to the actual donor. This would be extraordinarily difficult in practice. The wording in the relevant section of the EU legislative Annex (L38/45) is not in line with this interpretation.*

Article 5: *This paragraph suggests that procedures to identify providers and obtain consent for processing procured samples is not required if the provider happens to be the partner of the intended recipient. Is this wise?*

Draft Technical Annex 2 (Page 16)

Article 9: *Once again the traceability demands of 30 years will be considerable. Is this out of line with the 50 years demanded by HFEA currently and should there be alignment of this requirement.*

2. We would welcome views on the practical implications of compliance.

The introduction of QMS will present the biggest challenge for licensed and currently unlicensed centres. Although some centres have already acquired ISO 9001: 2000 certification recent QMS workshops held by the Society seem to suggest that there is at best considerable ignorance and at worst apathy about the rigorous demands of QM introduction. Many of those Quality managers in post and present at these workshops were unaware of the practical demands of QMS and felt in some instances unsupported by senior staff within the Units in which they worked.

The demands for IUI centres will be equally great. A number of centres have already indicated that they will no longer be able to provide services. Senior staff members in these units are unable to allocate financial and time resource to meet the demands of QMS introduction.

Units, which have invested in QMS, will be obliged to budget for set-up and running costs in their current and future business plans. Inevitably these costs will be passed on to patients with the probable effect that fewer patients will receive state funded treatment and waiting lists will increase.

Transposition

3. Do you have any views on our proposal to bring into force the Regulations and administrative provisions required to comply with the Directives?

The introduction of new regulations and administrative provisions as planned Is understood and acceptable to the sector.

The graduated approach to the timing of the first inspections under the new legislative requirements is sensible. A target of inspection of all Units by April 2009 should be achievable.

To grant a temporary licence to establishments not currently licensed by the

HFEA for a maximum of 2 years is also a pragmatic and sensible approach. Guidance to those centres In respect of minimum documentation to provide to the Authority In advance of such a decision will be required.

4. Do you have any views as to whether the transposition of these Directives into UK law will have any differential impact on ethnic groups?

Not that the BFS is aware of.

Regulatory Impact Assessment (RIA)

5. Do you have any comments on the assessment and the potential for any non-recurring (start up) and recurring costs associated with compliance?

As mentioned above the costs will be considerable for Units. The estimated costs as outlined are understandably speculative but unlikely to be far off the mark, particularly in relation to the QMS set-up and running costs.

There is a genuine concern in the sector on the impact this will have on the ability of the estimated 100 centres currently providing non-licensed activity. While some services will be taking place in CPA accredited laboratories, the need to set up QMS for clinical procedures and have a designated Person Responsible will undoubtedly put some Units off.

It is interesting to speculate as to whether the justification for imposing such rigorous and expensive demands on Units already struggling to provide comprehensive services bears evidence based scrutiny. Most in the sector would be reluctant to invest in new technologies or treatments if there was a dearth of evidence to support the change in practice. Best practice guidance from the BFS and other professional bodies would suggest that research evidence should be accumulate before committing to fundamental changes as being imposed in the Directive.

Consultation Criteria

6. Do you have comments on the extent to which the consultation criteria have been adhered to and suggestions of ways of further improving the consultation process?

No further comments.

Other Comments

7. Do you have any other comments on the proposals?

None