RESPONSE FROM THE INSTITUTE OF BIOMEDICAL SCIENCE ON THE DH CONSULTATION:

PROPOSALS TO TRANSFER FUNCTIONS FROM THE HUMAN FERTILISATION AND EMBRYOLOOGY AUTHORITY AND THE HUMAN TISSUE AUTHORITY

The Institute of Biomedical Science (IBMS) is the professional body for biomedical scientists working in the United Kingdom. It represents approximately 20,000 members employed mainly in the NHS pathology, blood, and health protection agency services in the UK, private laboratories, research, industry and higher education. The majority of its members are regulated by statute by the Health Professions Council under the protected title of Biomedical Scientist.

Consultation questions

1. **Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.**

   The Institute of Biomedical Science (IBMS) has concerns about the proposal and the impact its implementation could have on the services that currently fall within the jurisdiction of the HFEA and the HTA. The Care Quality Commission (CQC) is an organisation with a broad over-arching remit, very different in nature from the HFEA and HTA, which in contrast have a focused remit and associated clear body of expertise. The IBMS has considerable concern that transfer of functions to the CQC could reduce current standards of governance. The experience of this organisation is principally in respect of the HTA and there is an appreciation of its effectiveness in executing its remit. The HTA is recognised for its understanding and experience of pathology and mortuary services and the relationship that has developed to ensure safe, respectful and ethical handling and disposal of human tissues. There is concern that loss of the expertise within a much larger quality organisation could lead to a reduction of effectiveness and public confidence.

2. **Can you quantify what impact this could have at a local level (either in relation to service providers or patients or both)?**

   There is recognition of and respect for the inspection process used by the HTA. There is concern that transfer of the functions to the CQC could lead to less rigorous inspection regimens, less frequent inspections and of greatest concern, a loss of credibility within the international community for standards in handling human material within the UK.

3. **Do you agree that HFEA functions relating to research should be transferred to the HRA? Please explain why you think this.**

   Yes; the establishment of the HRA with the purpose to protect and promote the interests of patients and the public in health research was a significant step forward in regulation of research activity. In view of the effectiveness of the HRA it is the IBMS view that all research should come under one body, which could lead to the reduction of research overheads and improve efficiency.

4. **Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA? If so, which functions and which organisations and what do you see as the advantages of the alternative organisation?**

   The HTA has at its heart a confusion between regulating the 'donation consent' of human tissue (its prime directive) and its subsequent use as a human therapeutic product.
   Tissue obtained/stored in a HTA licensed Mortuary form part of pathological diagnosis and are not destined for use as a therapeutic product.
   Tissue obtained and subsequently prepared as a 'Therapeutic Product' should be controlled by the existing statutory body, the MHRA. The HTA has had to establish a regulatory system to control the use of biologic Therapeutic Products and as a consequence is duplicating a system already in place within the MHRA.
   Such a transfer of function in respect of human material destined for therapeutic product preparation could be achieved without the dissolution of the HTA and as a consequence deliver an efficiency saving. Both organisations would operate under the Human Tissue Act.

5. **Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies? Please explain why you think this.**

   This option could be explored further: it is possible that the administrative and managerial responsibilities of the two organisations could be merged, however it is likely the cost saving would be insignificant. Any required cost savings would need to be realistic, achievable and not to the detriment of the services delivered by the two organisations.

6. **Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? If so, please explain how and quantify**

   It is possible although savings are likely to be small. The two organisations were created with specific objectives and as such they discharge their respective responsibilities effectively and efficiently. An option would be to consider the transfer of functions associated with 'Therapeutic Products' to the MHRA (see question 4 response).

7. **Within the option of retaining the HFEA and the HTA as independent regulators, are there any of their functions you think should be transferred elsewhere and, if so, which and why?**

   All research functions within the HFEA & HTA should be transferred to HRA. Within the HTA, all therapeutic cell use should be transferred to MHRA

8. **Do you have any comments on our assessment of the efficiencies associated with the different options in paragraphs 154-158 above and in the accompanying consultation Impact Assessment?**

   Cost saving will only be achieved on a significant scale by the amalgamation of regulatory bodies. The CQC would need to TUPE all non-management staff, as they alone will have the necessary regulatory experience to continue the inspection work. It is likely that saving would only be achieved in the higher management levels.

9. **This consultation focuses specifically on where functions might sit and implementation will be at the discretion of the regulators. However, if you have any views as to how functions might be undertaken in future or other issues of concern that we could share with the bodies undertaking these functions as they plan for the future, please let us know.**

   The MHRA should consider the establishment of a Cellular Biologics section, handling the use of all therapeutic human cellular material, including blood (as it currently does), hospital transplant centres and the ATMP licences issued to Bio-Pharma and cell manufacturers. This would future proof regulatory work in Regenerative Medicine.

   There is some concern at the statement that “much of the detail of how functions would be carried out by recipient bodies would be for those organisations to decide”. Detailed and effective handover of functions (if such a decision is taken) is essential to maintaining a safe and effective regulatory service.

10. **Do you have any other comments on the consultation proposals that you would like to share with us?**

    In transferring some HFEA & HTA responsibility to the HRA, note needs to be taken of international (mainly USA) requirements for the use of human material in research. Human material is routinely exchanged all over the world and depriving UK research/ Bio-Pharma of human material has already had significant financial consequences.

11. **Can you provide examples of costs and benefits of these proposals?**

    This Consultation considers the functions of the regulators (para 162). This should have been the rationale for their original implementation many years ago. There

now exists an opportunity to reduce cost and improve regulatory management by devolving responsibility. The CQC was not established with HFEA & HTA functions in mind. The proposed options are still not addressing the functions of the regulators (para 162) and will not improve the current position.

12. Do you have any comments on the consultation Equality Analysis?

No. This concludes the response from the Institute of Biomedical Science.

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