Dear Mr Macdonald

Health and Sport Committee letter - EU Exit Regulations

Thank you for your letter of 4 October 2018 relating to the following regulations:

The Human Tissue (Quality and Safety or Human Application) (Amendment) (EU Exit) Regulations

The Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations

The HTA is unable to comment on the third set of regulations referred to in your letter [Blood Safety and Quality (Amendment) (EU Exit) Regulations], as these are not in the HTA's remit.

The HTA welcomes the Minister’s view that there is a strong argument for retaining consistent regulations across the UK to ensure ease of movement of tissues, cells and organs within the UK and to provide a coherent approach for the benefit of practitioners.

The HTA has not yet seen final versions of these SIs, but has been involved in regular discussions with the Department of Health and Social Care during the drafting process. The HTA is therefore only able to comment on the principles of the approach being proposed.

Our understanding is that the amendment SIs are drafted as a contingency in the event of a ‘no deal’ scenario, in which case the UK would become a ‘third country’. This would also necessitate that the UK consider EU Member States to be ‘third countries’. The HTA also understands that some of the provisions may be altered if a deal is reached.

For human tissue, this means that tissues or cells coming from/sent to EU countries will be treated as imports/exports, and that equivalent standards of quality and safety to those in place in the UK must be met. There may be some establishments who will therefore require a licence for import and/or export, who have not required this previously. The HTA anticipates that it will use established
licensing mechanisms for import, which rely on evidence including written agreements with suppliers. Whilst acknowledging that any increase in scrutiny over imports brings additional burden, the HTA does not consider that these regulations will create any further barriers of access given that EU countries are already working to equivalent standards, and that licensing mechanisms are already in place.

For organs for transplantation, this means that exchange of organs with EU countries must be adequately supervised to ensure that any organs exchanged can be traced from donor to recipient, and meet equivalent standards of quality and safety to those required under the current framework. The HTA has also had discussions with NHSBT in relation to agreements with other Member State authorities, which may facilitate the continued sharing of organs where appropriate. The HTA does not therefore consider that the proposed approach will create any barriers of access to organs.

As outlined above, the HTA sees benefit in maintaining a coherent UK wide approach to ensure continued ease of movement of tissues, cells and organs, support ongoing collaboration and co-operation between the organisations involved and minimise the disruption for practitioners. Ultimately this will help to ensure that patients continue to receive the human tissue and cell products, and organs, that they need.

I hope the above is helpful to the Committee in reaching a view. Please do not hesitate to contact me if you require further input or clarification.

Yours sincerely

[Signature]

Allan Marriott-Smith
Chief Executive Officer