16 October 2018

Response from Henny Braund, Chief Executive, Anthony Nolan

via email only

Dear Mr Macdonald,

Thank you for writing to me concerning these draft regulations, due to be laid before the UK Parliament next month. Anthony Nolan is the main importer and exporter of stem cells for patient transplant within the UK. Our operations have invested a significant amount of time in maintaining compliance with current UK Regulations and associated EU Directives.

With respect to the SIs, The Human Tissue (Quality and Safety for Human Application) (Amendment) (EU Exit) Regulations are relevant to our work in distributing stem cell products to transplant centres in the UK, Europe and across the World. We have yet to be approached for consultation by the Scottish Government and have so far shared our thinking on these draft regulations with the Department of Health and Social Care and the Human Tissue Authority, which I have outlined below:

**Regulatory management within the UK**

Within the constraints of a no deal scenario, we are supportive of all three health-related SIs and the proposal to cover these regulations at a UK level. This approach will go towards retaining consistent quality and safety standards across the UK, and is a general principle we would support for all no-deal planning in relation to tissue and cells.

I was pleased to see that the Minister, Joe Fitzpatrick MSP, is also content to support conferring existing European Commission regulatory responsibilities to UK Government departments. Patients’ access to lifesaving stem cells are best supported with a harmonised approach that sees one UK framework overseen by the Human Tissue Authority.

**Import / Export of stem cells between UK and EU countries**

The proposed regulations all state that without a deal, EU and EEA states would become ‘third countries’ for imports of tissues and cells to the UK. This requires us, as the importing tissue establishment to have specific agreements in place. The agreements will need to reflect that the EU establishments meet the UK regulatory requirements for the quality and safety of cells.

As we, and the EU establishments, currently meet the requirements of the EU Tissues & Cell Directives, this exercise will create added bureaucracy for our organisation. Unfortunately, the possibility of regulatory divergence going forward, which would introduce variability in regulatory requirements and uncertainty for patients, is an inevitable consequence of the proposed SIs.

Given the recent advice in the Technical Notice issued by the UK Government, Anthony Nolan is currently working with tissue establishments in EU countries to
secure written agreements that will provide proof of compliance with currently aligned quality and safety standards.

**Single European Code (SEC)**
Without a deal, the proposed SIs would see the removal of the requirement to use the Single European Code (SEC). For Anthony Nolan, losing this system of traceability across the EU would be hugely frustrating, as we have invested a considerable amount of time and funding into ensuring our compliance with the new SEC coding system.

However, we understand that an exit with no deal would mean that we no longer have access to the EU Compendium which facilitates the use of SEC. We would be losing a harmonised system for tracking tissues and cells imported / exported across the EU/EEA which is of considerable advantage to the safety of cells coming into the UK for patients.

As a consequence of the proposal, traceability within the UK will need to be re-examined by the Human Tissue Authority and DHSC; and we hope that the policy-makers will revert back to what we had prior to the introduction of SEC in April 2018 – the unique donor identification number. Any move to introduce a new domestic solution could prove costly and disruptive to the movement of stem cells within the UK; and abroad.

In place of any potential delay and disruption to stem cell supplies, we very much hope that a deal will be reached between the EU and UK Governments that maintains Human Tissue Authority oversight, regulatory alignment and continued traceability of cells across Europe.

We will continue to monitor developments in these draft regulations as well as the views of other key stakeholders. Will your Committee be publishing this response and for reference, could we be provided with copies of the responses received from other organisations? I look forward to hearing of the outcome of discussions and please do not hesitate in contacting me if you require anything further.

Yours sincerely,

Henny Braund
Chief Executive