

# Your Voice In Europe: ROADMAP feedback for Evaluation of Union legislation on blood, tissues and cells

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## Related document: Evaluation of Union legislation on blood, tissues and cells

### Feedback:

*NHSBT welcomes the proposed assessment of the EU legislation on blood, tissues and cells and would like the following comments to be considered in the roadmap, in line with the specific assessment criteria.*

*The EUBD is in need of significant update, but the EUTCD has generally been sufficiently adaptable to allow some development and innovation, although there have been some issues around overlap with ATMP legislation. It is often unclear what is acceptable without regulator clarification; particularly regarding starting materials for ATMP's. Interpretation of the Directives and standards differ across member states, e.g. a tissue in the UK may be deemed an ATMP or medical device in Germany.*

*The boundaries between tissues/cells and ATMP's are defined by Medicines regulation and often require regulator decisions. This has the potential to inhibit the expedient use of some novel types of ATMP's, which currently use the Hospital Exemption. There should be clear guidance, using a risk based approach, on the definition of a cell/tissue for transplant and an ATMP, in particular, definitions of non-homologous use and minimal manipulation. This can lead to big differences in the complexity and expense of regulation and testing requirements.*

*Serum (prepared from non-pooled individual donations autologous and allogeneic, undiluted or diluted for eye drops) is currently not included as a blood component for other therapeutic use in the EUBD, but should be. Autologous/Allogeneic Platelet-Rich Plasma is another example.*

*Decellularised tissues for transplantation should also be covered within the scope of the EUTCD.*

*The donor selection and testing criteria appears not to be based on current epidemiology, scientific principles or recent advances in testing. The EUBD (e.g. endoscopy) is more*

*restrictive (without clear supporting evidence) than EUTCD, e.g., the requirement of repeat testing for HTLV (in EUTCD) in live tissue donors does not have strong scientific rationale. Also, the haemodilution algorithm is outdated and should be reviewed.*

*There needs to be consideration of the increasing use of blood and tissue donations from altruistic donors as starting materials for manufacture of commercial products. How does this fit with the core principle of altruistic, non-remunerated donation of all tissue and cell products?*

*The legislation has provided a framework that has driven improvements in the quality and safety of blood and tissues for human application particularly in the Tissue and Cell area, where there was no previous regulatory oversight in some states. The legislation has introduced minimum common standards across Europe. It has made organisations responsible for ensuring sufficient resource is in place to meet these requirements and enabled greater information sharing and consistency across borders which is very beneficial and assists exchange of products. A drawback is that country-specific parameters e.g. local epidemiology, cannot be taken into account when making decisions on implementation of blood safety measures. Knowledge, skills and competency of the establishments and the competent authorities can be variable across Europe. To ensure a level playing field and consistency the competent authorities should agree common technical and quality standards and/or good practice guidelines.*

*Although there are no significant barriers to implementation, due to the complex nature of NHSBT, there are challenges in understanding and implementing some aspects of the legislation. There is overlap within organisations who are regulated against multiple directives and Competent Authorities, such as Blood Establishments also performing cell and tissue banking, and red cell reference testing under BSQR and UKAS. This has led to an increase in regulatory burden due to duplication of regulatory oversight. A routine 2 yearly inspection by Competent Authorities is quite burdensome. Longer inspection intervals based on risk should be considered as an alternative.*

*Cost-effectiveness is very difficult to assess as there is very little data available, but the directives have had an effect in terms of increasing costs and putting a significant additional burden on organisations to demonstrate compliance. What is not clear is to what extent this is equivalent across different states as there is no consensus between competent authorities on cost. There appears to be variation in the way regulators interpret and apply the directives and in the extent of the evidence they require. There have been significant cost implications initially for implementing traceability requirements, e.g., the requirement to introduce Eurocet SEC will add cost to establishments and the user hospitals to upgrade their IT systems.*

*Many operators in blood, tissues and cells seek accreditation to European and international standards e.g. JACIE, FACT nctcord or apply CoE Standards, which are generally higher and more detailed than the minimum standards set by the Directives. Exchange between accredited banks is preferred but if stricter national measures improve safety (e.g. NAT testing) that should be viewed as best practice. The Regulations should perhaps encourage accreditation to common European and international standards, or officially adopt these standards for certification/authorisation purposes.*

*The Directives should be reviewed at least every 3-5 years to keep the documents live and*

*relevant. The role of CoE guides should be considered for greater use as they are updated biannually and could replace the technical directives.*