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Central Procurement & Supplies Unit (CPSU)
Ministry for Health
UB002, Industrial Estate
San Ġwann, SĠN3000

Attn: Paul Mercieca

14 July 2022

Dear Mr. Mercieca,

Re: Legal Review of Legislation That May Barrier the New Establishment of Blood, Tissues and Cells (the 'EBTC Project')

1. Introduction

1.1. This Report (the '**Report**') has been prepared by Ganado Advocates of 171, Old Bakery Street, Valletta VLT 1455 ('**Ganado Advocates**'), pursuant to and in accordance with the Contract Agreement for the Provision of Services for Carrying Out of a Legal Review of Legislation that May Barrier the New Establishment of Blood, Tissues and Cells (EBTC) dated 28 April 2022 (the '**Public Contract**').

1.2. The subject-matter of the Report is to analyse and review any and all relevant legislation that may barrier the establishment or the functioning of the EBTC Project. A high-level preliminary report (the '**Preliminary Report**' attached and marked as '**Annex II**' to this Report) identifying the applicable legal framework has already been generated and approved by the Contracting Authority.

2. Terms of Reference

2.1. This Report is based on our review of:

(a) current and in-draft national and EU legislation on the subject of blood, tissues and cells as well as relevant secondary legislation regarding *inter alia* data protection and freedom of information, patient ethics and rights, and [*omissis*] (the '**Relevant Legislation**'); and

(b) the relevant policies (the '**NBTS Policies**') of the current National Blood Transfusion Service (the '**NBTS**').

(the Relevant Legislation and NBTS Policies shall hereinafter be referred to collectively as the '**Documents**'. The documents reviewed are indicated in a '**List of Reviewed Documents**' attached to this Report as '**Annex I**').

2.2. In view of the foregoing, this Report shall be split in two primary sections (the "**Scope**"):

(a) **Section 1**: a review of the Relevant Legislation to identify any legal barriers which may prevent the development or the functioning of the EBTC Project (or certain aspects of it) and to put forward recommendations that may help overcome them;

(b) **Section 2**: identification of the relevant NBTS Policies and determination of compliance with current [*omissis*] national and EU legislation.

2.3. This Report seeks to set out the legal matters which in our opinion are or may be relevant to you in terms of the Public Contract. Accordingly, in conducting our review of the Relevant Legislation and the Relevant Policies, we have exercised our judgement on a no-liability basis and included what we believe is likely to be materially relevant, whether directly or otherwise, to you in relation to the EBTC Project.

2.4. The assumptions, qualifications and reservations referred to below shall be applicable to all the sections of our Report and to any further advice or assistance given or occurring after the date of this Report. Therefore, any part, portion, segment or annexure of or to this Report shall always be considered as inseparable and integral parts of our Report and cannot be referred to or used independently. The Documents reviewed by us have been listed in Annex I of this Report.

3. Definitions

3.1. Below please find a list of further definitions specifically used in this Report:

blood	means whole blood collected from a donor and processed either for transfusion or for further manufacturing;
blood component	means a therapeutic constituent of blood (red cells, white cells, platelets, plasma) that can be prepared by various methods;
BTC	means blood, tissues and cells;
cells	means individual human cells or a collection of human cells when not bound by any form of connective tissue;
Contracting Authority	means the Central Procurement and Supplies Unit, Ministry for Health, UB002, Industrial Estate, San Ġwann SĠN3000;
distribution	means transportation and delivery of tissues or cells intended for human applications;
DNSH	means 'do no significant harm' as defined in Article 17 of Regulation (EU) 2020/852 of the European Parliament and of the Council of 18 June 2020 on the establishment of a framework to facilitate sustainable investment, and amending Regulation (EU) 2019/288;

Documents	means the Relevant Legislation and NBTS Policies as defined in this section. A List of Reviewed Documents is attached as Annex I to this Report;
donations	means donating human tissues or cells intended for human applications;
EBTC Project	means the Establishment of Blood, Tissues and Cells;
FOI Act	means the Freedom of Information Act, Chapter 496 of the Laws of Malta;
Ganado Advocates	means Ganado Advocates of 171, Old Bakery Street, Valletta VLT 1455;
GDPR	means General Data Protection Regulation (EU Regulation 2016/679);
human application	means the use of tissues or cells on or in a human recipient and extracorporeal applications;
NBTS	means the National Blood Transfusion Service, Pjazza San Luqa, Tal-Pietà;
NBTS Policy or NBTS Policies	means the policies and standard operating procedures adopted by the NBTS;
New Site	means Site SUB013 at Industrial Estate, Triq San Ġiljan, San Ġwann;

Patient	means a person who is receiving, or has received, medical attention, care, or treatment, whether in a healthcare setting or otherwise (Health Act, Chapter 528 of the Laws of Malta);
Pietà Site	means National Blood Transfusion Service, Guardamangia Hill, Pietà PTA1314;
Preliminary Report	means the high-level Phase I Report conducted by Ganado Advocates and approved by the Contracting Authority on 6 June 2022 to identify the Relevant Legislation and attached as Annex II to this Report;
preservation	means the use of chemical agents, alterations in environmental conditions or other means during processing to prevent or retard biological or physical deterioration of cells or tissues;
processing	means all operations involved in the preparation, manipulation, preservation and packaging of tissues or cells intended for human applications;
procurement	means a process by which tissue or cells are made available;
Public Contract	means the Contract Agreement for the Provision of Services for Carrying Out a Legal Review of Legislation that May Barrier the New Establishment of Blood, Tissues and Cells (EBTC) dated 28 April 2022 and entered into between the Contracting Authority and Ganado Advocates;
Relevant Legislation	means current and in-draft national and EU legislation on the subject of blood, tissues and cells as well as relevant secondary legislation identified by Ganado Advocates as being relevant to the development or functioning of the EBTC Project;

Report	means this Phase II report;
RRF	means the EU's Recovery and Resilience Facility as established under Regulation (EU) 2021/241 of the European Parliament and of the Council of 12 February 2021 establishing the Recovery and Resilience Facility;
[*omissis*]	[*omissis*]
SPH	means the Superintendent of Public Health;
storage	means maintaining the product under appropriate controlled conditions until distribution;
TFEU	means the Treaty on the Functioning of the European Union;
tissue	means all constituent parts of the human body formed by cells;
validation	means establishing documented evidence that provides a high degree of assurance that a specific process, piece of equipment or environment will consistently produce a product meeting its predetermined specifications and quality attributes; a process is validated to evaluate the performance of a system with regard to its effectiveness based on intended use;
[*omissis*]	[*omissis*]
Waste Framework Directive	means Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on Waste and Repealing Certain Directives.

4. Issues

4.1. Next to each item raised, we have included our recommended course of action which shall consist in a variation of the following:

i. the proposal of a workaround solution to circumvent the bottleneck;

ii. the proposal of legislative amendments to address and remove the bottleneck;

iii. the deletion or amendment of the NBTS Policy according to its risk level;

iv. the addition of a new NBTS Policy;

v. the suggestion of legislative intervention;

vi. for information purposes only; or

vii. not applicable.

Our assessment and recommendations are provided below.

SECTION 1: REVIEW OF THE RELEVANT LEGISLATION AND RECOMMENDATIONS

CATEGORY A: BLOOD, TISSUES AND CELLS

	LEGISLATION	RELEVANCE, BARRIER AND RECOMMENDATION
1.	MT: Human Blood and Transplants Act (Chapter 483 of the Laws of Malta) MT: Human Blood and Transplants (Fees) Regulations (Subsidiary Legislation 483.09 of the Laws of Malta)	**RELEVANCE**: This Act lays down the basic definitions used in blood, tissues and cells legislation. It also lays down the powers of the SPH to grant, revoke, and process applications for, licences to blood establishments and tissues and cells establishments. The activities which require licensing are the following: (a) collection and testing of human blood components; (b) the preparation, storage, and distribution of human blood components (when intended for transfusion); and (c) any activity in connection with the testing, processing, preservation, storage, and distribution of tissues and cells intended for human applications. No licence is required: (a) if the person carrying out the above licensable activities is doing so on behalf of a licensed establishment; (b) when done for storage and distribution of, and the performance of compatibility tests on, blood, blood components, tissues and cells exclusively for use in hospital facilities (e.g. applicable to hospital blood banks established as a hospital unit within the relevant hospital facility). This exclusion applies only to hospital blood banks. Since NBTS is not licensed as a hospital facility and is not a hospital blood bank, then it cannot rely on this exemption, even if it were to carry out these activities on behalf of a hospital facility; (c) when done for the direct distribution of specified tissues and cells for immediate transplantation to the patient if the supplier of the said tissues and cells is licensed for such an activity.

		The prior written approval of the SPH is required where the establishment is affecting a 'substantial change' to its operating sites or activities. Articles 5(12) and 12(11) respectively set out what would amount to a substantial change in a blood establishment and tissue and cell establishment. Lastly, it is possible to import blood or tissues and cells from third countries provided that compliance with the quality standards mandated in Directive 23/2004/EC[1] (as amended) and Commission Directive 33/2004,[2] respectively, is assured and traceability requirements are satisfied. **BARRIER**: We do not perceive this Act to present any particular barrier for the EBTC Project. However, for this purpose we have examined the current licences granted to NBTS by the SPH. This review is included in Section 2 below and in summary, it is our view that NBTS would (by way of a "substantial change") need to extend its existing licence for its tissue and cells establishment to cover these new services envisaged under the EBTC Project, or alternatively, seek a new licence altogether. **RECOMMENDATION**: We recommend that the prior written approval of the SPH is obtained before NBTS starts operating from the new site and/or offering the new services. SPH will guide NBTS whether an extension of the licence can be issued or whether a new licence is required. This is based on two factors: (a) since the EBTC Project shall be installed at the New Site and (b) NBTS shall be introducing new activities e.g. HLA typing, stem cell banking, and bone banking (both of which would constitute a "substantial change" to its current licence/s and approved licensed activities). The application for approval to make a substantial change in activities must be accompanied by the fee of EUR 2,500 in terms of Regulation 3 of the Human Blood and Transplants (Fees) Regulations (Subsidiary Legislation 483.09 of the Laws of Malta).

[1] Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells.

[2] Commission Directive 2004/33/EC of 22 March 2004 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards certain technical requirements for blood and blood components.

2.	EU: Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC	**RELEVANCE**: This Directive lays down the foundations for the quality and safety of whole blood and blood components. For the most part, it is already transposed into Maltese law, including under the Human Blood and Transplants Act (Chapter 483 of the Laws of Malta), but it is interesting to note the following provisions: (a) the recommendation in favour of voluntary and unpaid donations and the option bestowed on Member States to enact legislation which will encourage such donations; (b) the requirement for a blood establishment to appoint a 'responsible person' for ensuring compliance with the relevant laws; (c) the requirement to maintain statistical information e.g. total number of blood donations and total number of adverse reactions for 15 years; (d) the requirement to maintain data required to ensure traceability for 30 years; (e) the duty to enact measures to anonymise data to which third parties have access. **BARRIER**: Not applicable since this Directive has been transposed in the Act and its subsidiary legislation (which will be examined in further detail below). **RECOMMENDATION**: For information purposes only.
3.	EU: Commission Directive 2004/33/EC of 22 March 2004 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards certain technical requirements for blood and blood components	**RELEVANCE**: This Directive implements the groundwork established in Directive 2002/98/EC. It sets out the following: (a) information to be given to prospective donors; (b) information to be obtained from actual donors; (c) eligibility criteria to be a donor; (d) the procedure for storage, transport and distribution of whole blood and blood components; and (e) the quality and safety requirements of whole blood and blood components.

		BARRIER: Not applicable since this Directive has been transposed in the Act and its subsidiary legislation (which will be examined in further detail below). **RECOMMENDATION**: For information purposes only.
4.	EU: Commission Implementing Directive 2011/38/EU of 11 April 2011 amending Annex V to Directive 2004/33/EC with regards to maximum pH values for platelets concentrates at the end of the shelf life	**RELEVANCE**: Not applicable (based on our understanding of the planned services). This primarily amended the maximum pH value for platelet concentrates in Annex V of Directive 2004/33/EC. **BARRIER**: Not applicable. **RECOMMENDATION**: Not applicable.
5.	Commission Directive 2014/110/EU of 17 December 2014 amending Directive 2004/33/EC as regards temporary deferral criteria for donors of allogeneic blood donations	**RELEVANCE**: This concerns the possibility of applying a nucleic acid test to determine the application of temporary deferral to donors leaving an area with ongoing transmission of West Nile Virus to humans. **BARRIER**: NBTS must ensure compliance. **RECOMMENDATION**: For information purposes only.
6.	EU: Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation,	**RELEVANCE**: This Directive mirrors Commission Directive 2004/33/EC on the quality and safety of blood and blood components. It establishes standards for all stages involved in the processing of tissues and cells. Aside from requirements similar or equivalent to the blood-regulating Directive, it is interesting to note the following: (a) the recommendation in favour of voluntary and unpaid donations of tissues and cells is repeated in stronger wording here. This Directive also goes a step further in that it strictly limits compensation to 'the making good [of] expenses and inconveniences related to the donation';

	storage and distribution of human tissues and cells	(b) the quality system of a tissues and cells establishment must contain: (i) standard operating procedures (ii) guidelines (iii) training and reference manuals (iv) reporting forms (v) donor records (vi) information on final destination; and (c) any external activity involving a third party and which may influence the quality and safety of tissues and cells must be recorded in written agreements. **BARRIER**: We do not perceive this legislation to present any specific barrier for the EBTC Project. That said, we do wish to highlight that it establishes that compensation to donors is an exception to the rule, and even then, it is strictly limited. [*omissis*] **RECOMMENDATION**: For information purposes only. Note that all activities affecting the quality or safety of tissues and cells that have been outsourced or delegated to third parties must be recorded in written agreements. Therefore, it is incumbent upon NBTS to ensure that any such existing arrangements which it has with third parties, and any future arrangement which it may enter into in regard to the EBTC Project, are recorded and formalised by means of a written agreement. [*omissis*]
7.	EU: Commission Directive 2005/62/EC of 30 September 2005 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards Community standards and specifications relating to a quality system for blood establishments	**RELEVANCE**: The Annex to this Directive establishes the standards and specifications of the quality system to be implemented by blood establishments throughout the EU. **BARRIER**: Member States were obliged to transpose the contents of this Directive by August 2006. Malta enacted Legal Notice 272 of 2006 (nowadays the Blood (Quality and Safety) Regulations (Subsidiary Legislation 483.02 of the Laws of Malta) to implement the standards and specifications of the blood establishment's quality system as required by this Directive. **RECOMMENDATION**: For information purposes only.
8.	EU: Commission Directive 2016/1214 of 25 July 2016	**RELEVANCE**: This Directive requires Member States to implement good practice guidelines for blood establishments, and in doing so take into account the Good Practice Guidelines, included in the Guide to

	amending Directive 2005/62/EC as regards quality system standards and specifications for blood establishments	the preparation, use and quality assurance of blood components, Appendix to Recommendation No. R (95) 15 of the Committee of Ministers on the preparation, use and quality assurance of blood components adopted on 12 October 1995 (the '**Good Practice Guidelines**'). Regulation 10 of the Blood (Quality and Safety) Regulations (Subsidiary Legislation 483.02 of the Laws of Malta) mirrors this obligation to take into account the Good Practice Guidelines. **BARRIER**: [*omissis*] Compliance [*omissis*] must be ensured. **RECOMMENDATION**: Not applicable.
9.	MT: Blood (Quality and Safety) Regulations (Subsidiary Legislation 483.02 of the Laws of Malta)	**RELEVANCE**: These Regulations implement provisions of: (a) Directive 2002/98/EC (b) Commission Directive 2004/33/EC and Directive; (c) Commission Directive 2005/62/EC and Commission Directive 2016/1214. **BARRIER**: NBTS must ensure compliance. **RECOMMENDATION**: For information purposes only.
10.	EU: Commission Directive 2005/61/EC of 30 September 2005 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards traceability requirements and notification of serious adverse reactions and events	**RELEVANCE**: This Directive sets down the requirement of traceability i.e. the ability to trace blood or blood component from the donor to their final destination, as well as the format for notification of serious adverse reactions and events. **BARRIER**: No particular barrier for the EBTC Project. **RECOMMENDATION**: For information purposes only.

11.	MT: Traceability Requirements and Notification of Serious Adverse Reactions and Events Regulations (Subsidiary Legislation 483.03 of the Laws of Malta)	**RELEVANCE**: These Regulations transpose Directive 2005/61/EC i.e. the requirements of traceability and the notification of serious adverse reactions and events. **BARRIER**: No barrier, but NBTS must implement and adhere to its requirements. **RECOMMENDATION**: For information purposes only.
12.	EU: Commission Directive 2009/135/EC of 3 November 2009 allowing temporary derogations to certain eligibility criteria for whole blood and blood components donors laid down in Annex III to Directive 2004/33/EC in the context of a risk of shortage caused by the Influenza A(H1N1) pandemic MT: Blood Supply (Temporary Derogations to Eligibility Criteria) Regulations (Subsidiary Legislation 483.05 of the Laws of Malta)	**RELEVANCE**: None. This Directive applied only until 30 June 2010 to ease donor eligibility criteria as a means of combatting the shortages in blood and blood components caused by the influenza pandemic. The Maltese Regulations mirrored this Directive. **BARRIER**: Not applicable. **RECOMMENDATION**: Not applicable.
13.	EU: Stakeholder Workshop with Blood Competent Authorities on 'Regulating	**RELEVANCE**: This is not legislation, but it was a workshop organised by the Substances of Human Origin Expert Group to discuss the Impact Assessment which was published in the wake of the Commission's evaluation of the Union legislation on blood, tissues and cells. A number of legislative recommendations

	for Sufficiency – Blood and Plasma' held on 4 May 2021	were put forward, including: (a) mandatory routine reporting of sufficiency data (b) mandatory emergency and contingency plan requirements and (c) distinction between blood-derived and plasma-derived products. These are likely to be included or addressed in the Commission's new draft legislation which has been slated for July 2022. **BARRIER**: None. We will be in a position to opine on its (potential) impact and provided recommendations (as needed) upon publication of the upcoming BTC legislation.
14.	EU: Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells	**RELEVANCE**: This Directive has been in part transposed by the Tissue and Cells (Quality and Safety) Regulations (Subsidiary Legislation 483.01 of the Laws of Malta). Interestingly, this Directive expressly excludes autologous grafts from its scope, as well as blood, blood components and organs. The exclusions are also present in Maltese law, specifically under the Human Tissues and Cells (Coding, Processing, Preservation, Storage and Distribution) Regulations (Subsidiary Legislation 483.04 of the Laws of Malta). Clause 2.1.1 of Schedule 2 to the Regulations states that the same biological testing requirements are to be applied to the storage and culturing of autologous and allogeneic donations. This is a transposition of Clause 2.1.1 of Annex 1 to Commission Directive 2006/17/EC[3] as discussed below. Member States retain discretion to gold-plate requirements, including the imposition of prohibitions of imports and/or tissues and cells from a specified source to ensure a healthy supply of tissues and cells. Member States can also undertake measures necessary to encourage voluntary and unpaid donations. The Directive goes further and states that donors may receive compensation, which is strictly limited to making good the expenses and inconveniences related to the donation. The conditions of compensation themselves however, are within the discretion of the Member State itself. The Directive also stipulates numerous requirements which are reflected in the local Regulations, such as traceability and labelling requirements, the notification procedures for serious adverse events and

[3] Commission Directive 2006/17/EC of 8 February 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells.

		reactions, the responsible person requirement, and the proper qualifications and training of the personnel involved. Importantly, the Directive mandates that Member States follow the Commission rules on *inter alia* licensing, procurement of tissues and cells, quality systems, selection criteria, and processing, storage and distribution requirements. **BARRIER**: NBTS must ensure compliance. **RECOMMENDATION**: For information purposes only.
15.	Commission Directive 2006/17/EC of 8 February 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells	**RELEVANCE**: This Directive lays down the quality and safety requirements of all tissues and cells, including those used as starting material for the manufacture of medicinal products. It also lays down: (a) the selection criteria for donors of tissues and/or cells (b) the laboratory tests required for donors (c) the selection criteria and laboratory tests for donors of reproductive cells and (d) cell and/or tissue donation and procurement procedures. **BARRIER**: NBTS must ensure compliance. **RECOMMENDATION**: For information purposes only.
16.	EU: Commission Directive 2012/39/EU of 26 November 2012 amending Directive 2006/17/EC as regards certain technical requirements for the testing of human tissues and cells	**RELEVANCE**: This Directive amends the requirement of HTLV-I antibody testing in donors from 'high-incidence' to donors from 'high-prevalence' areas and allows testing on donors of reproductive cells to be carried out at fixed time intervals throughout a 24-month period instead of at the time of each donation. **BARRIER**: NBTS must ensure compliance. **RECOMMENDATION**: For information purposes only.
17.	MT: Tissues and Cells (Quality and Safety) Regulations (Subsidiary	**RELEVANCE**: These Regulations are the tissues and cells equivalent of the Blood (Quality and Safety) Regulations (Subsidiary Legislation 483.02 of the Laws of Malta). They establish the responsible person requirement, the duties of the tissues and cells establishment (including proper and regular training of qualified personnel, the testing of tissues and cells, the labelling and identification requirements, the

	Legislation 483.01 of the Laws of Malta)	notification of serious adverse events and reactions, informing and obtaining information on donors and the encouragement of voluntary unpaid donations). These Regulations also stipulate the need for quality management, and for procurement of tissues and cells to be carried out solely by qualified personnel (i.e. clinical team specialising in said tissue or cell) and in accordance with strict written procedures. The annexed Schedules also lay out the selection criteria of donors of reproductive cells specifically and of tissues and cells generally. Lastly, the SPH may authorise the direct distribution of specific tissues and cells from where the procurement is carried out to a health care establishment for immediate transplantation. **BARRIER**: No particular barrier for the EBTC Project NBTS must however ensure compliance. **RECOMMENDATION**: For information purposes only.
18.	EU: Commission Directive 2006/86/EC of 24 October 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells	**RELEVANCE**: This Directive applies to the coding, processing, preservation, storage and distribution of: (a) tissues and cells intended for human applications; and (b) manufactured products derived from human tissues and cells intended for human applications, where those products are not covered by other directives. Both tissues and cells and the manufactured products must be traceable from procurement to human application or disposal. It also establishes the Single European Code which is the unique identifier applied to tissues and cells distributed in the EU. The Annexes to the Directive lay down the following: (a) requirements for accreditation, designation, authorisation or licensing of tissue establishments; (b) requirements for the authorisation of the preparation processes at tissue establishments; (c) format for notification of serious adverse reactions and events; and (d) the minimum data to be retained on the donor to enable traceability. **BARRIER**: No particular barrier for the EBTC Project NBTS must however ensure compliance. **RECOMMENDATION**: Provided for information purposes only, but please refer to the sections on the local laws transposing the provisions of this Directive.

19.	EU: Commission Directive (EU) 2015/565 of 8 April 2015 amending Directive 2006/86/EC as regards certain technical requirements for the coding of human tissues and cells	**RELEVANCE**: This Commission Directive amends Directive 2006/86/EC with regard to the traceability requirements and harmonisation of the Single European Code. **BARRIER**: Not applicable. **RECOMMENDATION**: Not applicable.
20.	EU: Commission Directive (EU) 2015/566 of 8 April 2015 implementing Directive 2004/23/EC as regards the procedures for verifying the equivalent standards of quality and safety of imported tissues and cells	**RELEVANCE**: This Commission Directive applies to the importation of tissues and cells, both in their original form and as manufactured products. It provides for the obligations on importing tissue establishments and the minimum requirements to be met by the third-country supplier or sub-contractor and the importing tissue establishment. **BARRIER**: The importation of tissues and cells from third countries (i.e. outside the EU) can be undertaken only by importing establishments authorised specifically for the purpose of this activity. The only two exceptions are imports which are directly authorised by the SPH and emergency imports. Establishments which are so licensed are issued with, and should be in possession of, a document entitled 'Certificate of Accreditation, Designation, Authorisation, or Licence to be issued by the competent authority or authorities to importing tissue establishments' (the '**Importation Certificate**'). Schedule 2 to the Directive provides a template of this certificate. [*omissis*] **Exports (for information purposes):** Article 9 of Directive 23 of 2004 governing tissues and cells regulates the import/export of human tissues and cells. In particular, sub-paragraph (2) states that: "*Member States shall take all necessary measures to ensure that all exports of tissues and cells to third countries are undertaken by tissue establishments accredited, designated, authorised or licensed for the purpose of those activities. Those Member States that send such exports to third countries shall ensure that the exports comply with the requirements of this Directive.*

		[*omissis*]
21.	MT: Equivalent Standards of Quality and Safety of Imported Tissues and Cells Regulations (S.L. 483.08 of the Laws of Malta)	**RELEVANCE**: These Regulations transpose Commission Directive 2015/566/EU. Schedule 1 sets out the minimum requirements concerning the information and documentation to be provided by importing tissue establishment applicants when applying to be accredited, designated, authorised or licensed for the purpose of import activities. **BARRIER**: Same as that concerning Commission Directive 2015/566/EU. [*omissis*]
22.	EU: Commission Decision of 3 August 2010 establishing guidelines concerning the conditions of inspections and control measures, and on the training and qualification of officials, in the field of human tissues and cells provided for in Directive 2004/23/EC of the European Parliament and of the Council	**RELEVANCE**: This Commission Decision sets out the qualification and training requirements of inspectors and the procedures that inspections have to follow. These include, for instance, the requirement for inspections to be carried out at least once every two years and to avoid inspections by a single inspector. **BARRIER**: Not applicable. **RECOMMENDATION**: Not applicable.
23.	Commission Decision of 3 July 2015 establishing a model for agreements between the Commission and relevant organisations on the provision of product codes for use in the Single European Code	**RELEVANCE**: This Decision adopts a model agreement between organisations which manage product codes for tissues and cells and such manufactured products and the European Commission on the provision of product codes for use within the Single European Code. **BARRIER**: Relevant for exporting. **RECOMMENDATION**: Relevant for exporting.

24.	MT: Human Tissues and Cells (Coding, Processing, Preservation, Storage and Distribution) Regulations (Subsidiary Legislation 483.04 of the Laws of Malta)	**RELEVANCE**: A tissue establishment is required to comply with the Schedule 1 requirements to obtain a licence, which can be split up into 6 categories: (a) organisation and management (e.g. the 'responsible person' requirement) (b) personnel (e.g. the requirement for updated training) (c) equipment and materials (e.g. preventative maintenance) (d) facilities/premises (e.g. the requirement for suitable facilities including clean rooms) (e) documentation and records (e.g. the need for a document control procedure) and (f) quality review i.e. an audit to verify that the standards of quality and safety for the activities which the tissue and cells establishment is licensed to carry out are being adhered to. The preparation processes of tissues and cells must comply with the Schedule 2 requirements, which can also be split up into 6 categories: (a) reception of tissues and cells at the establishment (e.g. quarantine of tissues and cells pending inspection requirement) (b) processing (e.g. compliance with approved standard operating procedures) (c) storage and release of products (e.g. specification of maximum storage time for each type of storage condition) (d) distribution and recall (e.g. the container must be secure to ensure that its contents are maintained in specified conditions) (e) final labelling for distribution (e.g. the need to provide certain information on the label or in accompanying documentation such as the expiry date) and (f) external labelling of the shipping container (e.g. the shipping container in which the primary container is placed must be labelled with certain information such as a 'HANDLE WITH CARE' statement). Furthermore, the Regulations stipulate that the tissue establishment must retain certain data on human applications for at least 30 years, using an appropriate and readable storage medium. The data retained (e.g. unique donation number and the Single European Code) will enable traceability of the tissues and cells from the recipient to the donor. **BARRIER**: Currently, NBTS only has a licence authorising donation, procurement, testing, processing, preservation, storage and distribution of tissues and cells intended for cornea transplantation. Therefore, the requirements stipulated in these Regulations must be considered and adhered to when applying to extend its existing licence and providing the new services to be introduced by the EBTC Project (insofar as tissues and cells are concerned). NBTS must ensure compliance.

		RECOMMENDATION: Please refer to the section below on the licence issued by the SPH to NBTS on the tissues and cells establishment.
25.	MT: Human Organs, Tissues and Cell Donation Act (Chapter 558 of the Laws of Malta)	**RELEVANCE**: This Act is secondary to any and all legislation enacted in terms of Chapter 483 of the Laws of Malta, and does not apply to autologous donations of tissues and cells or embryo donations. This Act establishes a National Human Organ and Tissue Donation Register to be maintained by the SPH and which shall contain a list of individuals who express their wish to donate or otherwise their tissues and cells following their death, and the particular tissues and cells which an individual wishes to donate or not. It is also possible for individuals to inform the Registrar of their wish to be living donors. [*omissis*]

CATEGORY B: EQUALITY AND ACCESSIBILITY

	LEGISLATION	RELEVANCE, BARRIER AND RECOMMENDATION
1.	EU: Council Directive 2004/113/EC implementing the principle of equal treatment between men and women in the access to and supply of goods and services	**RELEVANCE**: The purpose of this Directive is to prevent and eliminate both direct and indirect discrimination based on sex, including harassment and sexual harassment, in the area of the access to and supply of services. **BARRIER**: None envisaged. **RECOMMENDATION**: For information purposes only.
2.	MT: Access to Goods and Services and their Supply (Equal Treatment) Regulations (Subsidiary Legislation 456.01 of the Laws of Malta)	**RELEVANCE**: The purpose of these Regulations is to give effect to Council Directive 2004/113/EC implementing the principle of equal treatment between men and women in the access to goods and services and their supply. These are applicable to NBTS as a provider of services to the public and prohibit both direct and indirect discriminatory treatment related to pregnancy or maternity, which includes harassment and sexual harassment. The caveat to be drawn here is that positive action, that is measures adopted with a view to combating disadvantages linked to sex, are permitted. **BARRIER**: No barrier is envisaged. NBTS will be obliged to adhere to these Regulations. **RECOMMENDATION**: For information purposes only.
3.	Council Directive 2000/43/EC implementing the principle of equal treatment between persons irrespective of racial origin	**RELEVANCE**: This Directive prohibits direct or indirect discrimination based on racial or ethnic origin, including harassment. It is applicable to access to and supply of services which are available to the public. **BARRIER**: None envisaged.

		RECOMMENDATION: For information purposes only.
4.	MT: Equal Treatment of Persons Order (Subsidiary Legislation 460.15 of the Laws of Malta)	**RELEVANCE**: The purpose of this Order is to give effect to Council Directive 2000/43/EC implementing the principle of equal treatment between persons irrespective of racial or ethnic origin. NBTS is prohibited from discriminating against any other person in relation to healthcare and access to the supply of services available to the public. Advertisements promoting discrimination are also prohibited. Any person found guilty of an offence under this Order is liable on conviction to a fine of EUR 2,329.37 or to imprisonment for not more than six months, or to both such fine and imprisonment. Upon a complaint being lodged, NBTS would be obliged to draw up a report on the complaint and steps taken to verify or investigate the same and to circulate the same to the complainant or to the Equality Commission. The onus of proof is inverted in such cases which effectively means that the burden would be on NBTS to prove the absence of discrimination. **BARRIER**: No barrier is envisaged. NBTS will be obliged to adhere to these Regulations. **RECOMMENDATION**: For information purposes only.
5.	MT: Bill entitled the 'Equality Act, 2019' (not yet law)	**RELEVANCE**: The purpose of this bill is to enact a codified Act which brings together Chapter 456 of the Laws of Malta and all subsidiary legislation relating to discrimination. The full title of the draft Act makes reference to a number of EU Directives, including the above-mentioned Council Directive 2004/113/EC and Council Directive 2000/43/EC, as well as Council Directive 2000/78/EC establishing a general framework for equal treatment in employment and occupation, and Council Directive 2006/54/EC implementing the principle of equal opportunities and equal treatment of men and women in matters of employment and occupation (recast). Most notably, this bill introduces the concept of 'protected characteristics', that is, age, belief, creed or religion, colour, ethnic or national origin, disability, family responsibilities or pregnancy, family or civil status, gender expression or gender identity, genetic features, health status, language, nationality, political opinion, property, sex or sex characteristics, sexual orientation, and social origin.

		The draft Act also caters for several exceptions to the rule which are not deemed to constitute discrimination. These include less favourable treatment on the basis of a protected characteristic which is reasonable, proportionate, and legitimate or where the characteristic constitutes a genuine and determining requirement which is also legitimate and proportionate. **BARRIER**: No barrier envisaged. NBTS will be obliged to adhere to these Regulation. NBTS should be mindful of the current permanent deferral criterion for donors of allogeneic donations, that is, persons whose sexual behaviour puts them at high risk of acquiring severe infectious diseases that can be transmitted by blood. This is mandated by Directive 2004/33/EC implementing Directive 2002/98/EC as regards certain technical requirements for blood and blood components. More generally, this draft Act is to be taken into account in the selection of donors process. **RECOMMENDATION**: No barrier envisaged, but we suggest keeping tabs on the promulgation of this draft Act, as it may also be relevant for donor selection criteria and purposes.
6.	(a) Charter of Fundamental Rights of the European Union (b) European Convention on Human Rights	**RELEVANCE**: The Charter establishes a number of principles including non-discrimination, equality between men and women, and the integration of persons with disabilities. It also lays down the right of access to health care. Similarly, Article 14 of the Convention lays down the principle against discrimination in the enjoyment of rights and freedoms. **BARRIER**: None envisaged. **RECOMMENDATION**: For information purposes only.
7.	MT: Health Act (Chapter 528 of the Laws of Malta)	**RELEVANCE**: This Act reiterates the establishment of the national health system on principles including equity and accessibility. **BARRIER**: Not applicable. **RECOMMENDATION**: Not applicable.

8.	MT: Equality for Men and Women Act (Chapter 456 of the Laws of Malta) MT: Employment and Industrial Relations Act (Chapter 452 of the Laws of Malta)	**RELEVANCE**: The unlawfulness of discrimination or sexual harassment at the workplace is established in the Employment and Industrial Relations Act. The Equality for Men and Women Act reiterates and sets out: (a) the prohibition against discrimination in employment and sexual harassment (b) the employer's obligation to report sexual harassment or discrimination and (c) the prohibition against discriminatory advertisement. **BARRIER**: None envisaged. NBTS will have to ensure compliance. **RECOMMENDATION**: For information purposes only.

CATEGORY C: DATA PROTECTION AND FREEDOM OF INFORMATION

	LEGISLATION	RELEVANCE, BARRIER AND RECOMMENDATION
1.	MT: Freedom of Information Act (Chapter 496 of the Laws of Malta)	**RELEVANCE**: The Freedom of Information Act provides the public with the right to request access to information held by public authorities. The stated objective of this legislation is to promote added transparency and accountability in government, and the Act pursues and implements this in two particular ways: i. public authorities are obliged to publish certain information about their functions and activities (see Part III, FOI Act); and ii. it grants "eligible persons"[4] the right to, as a legal entitlement, request information from public authorities. Public authorities are in turn, subject to limited exceptions, required to fulfil FOI requests and to disclose the requested information. [*omissis*] As mentioned, this right of access is directed at "public authorities", which the FOI Act defines as comprising any of the following: i. the Government, including any ministry or department thereof; ii. a Government agency established in terms of the Public Administration Act; iii. any body established under any law, or any partnership or other body in which the Government, a Government agency or any such body has a controlling interest or over which it has effective control.

[4] Defined in the FOI Act as "a person who is resident in Malta and who has been so resident in Malta for a period of at least five years, and who is either a citizen of Malta or a citizen of any other member state of the European Union or a citizen of any other state the citizens of which have a right, in virtue of any treaty between such state and the European Union, to be treated in Malta in the same manner as citizens of member states of the European Union."

		In that respect, we understand that NBTS is constituted within the Ministry for Health,[5] and therefore falls within the definition of a public authority under limb '(i)' (that is, "*the Government, including any ministry or department*"). Consequently, FOI requests may be directed to NBTS by the public, including in relation to this proposed EBTC Project and, for its part, NBTS would be obliged to observe and apply the provisions of the FOI Act, including its rules on disclosure. **BARRIER**: [*omissis*] [*omissis*] it is our view that the EBTC Project should not result in much (if any) change in practice for NBTS in terms of FOI legislation and related obligations. NBTS will remain obligated to observe the procedures and timeframes prescribed in the FOI Act upon receiving FOI requests (see articles 10 & 11). Rules on exempt documents would also need to be considered. In particular, NBTS would need to ensure that it does not disclose, and has procedures in place to prevent disclosing, personal data of any donors or patients using the services of the EBTC Project (an obligation which equally applies in relation to its blood establishment). This stems from (i) article 5 of the FOI Act (which *inter alia* states that "personal data" is excluded from the scope of the FOI Act) and (ii) regulations 9 and 10 respectively of the Blood (Quality and Safety Regulations) and Tissues and Cells (Quality and Safety) Regulations. **RECOMMENDATION**: For information purposes; [*omissis*]
2.	EU: General Data Protection Regulation (EU Regulation 2016/679)	**RELEVANCE**: As a member of the EU, the GDPR is directly applicable in Malta and therefore binding in its entirety under Maltese law, without the need for local transposition. It applies to *inter alia* the processing of personal data by any natural or legal person, public authority, public agency or other body established in the EU, and thus NBTS falls within its territorial scope of application. The GDPR applies to both data "controllers" and "processors". Broadly speaking, a data controller (as defined in the regulation) determines the purposes and the means/manner in which personal data is

[5] Ministry for Health, 'Freedom of Information': <https://deputyprimeminister.gov.mt/en/Pages/Freedom-Of-Information.aspx>.

		processed. Data processors, on the other hand, are third parties who undertake data processing on behalf of a controller. Classification in this context is quite key, since differing obligations apply to controllers and processors in the GDPR. We consider that NBTS largely acts as a data controller in respect of its blood and cornea establishments, and that it would be subject to this same controller classification in regard to the EBTC Project and its extended services. As a data controller, NBTS must adhere to a myriad of data protection obligations and duties contained in the GDPR, including non-exhaustively: (i) compliance with fundamental data processing principles, including data minimisation, transparency, accountability, storage limitation (article 5); (ii) respecting individual's data subject rights (section 2); (iii) ensuring data security by adopting appropriate technical and organisational measures (article 24); (iv) engaging appropriate processors and having processor contracts in place (article 28); (v) notification of personal data breaches (article 33); (vi) appointment of a data protection officer ("**DPO"**) as a public authority and conducting data protection impact assessments ("**DPIA"**) (articles 35 and 37). There are also further conditions on the processing of special categories of personal data, which are particularly relevant for NBTS given the nature of its activities and services and the type of data which it routinely processes (health / genetic data). **BARRIER**: [*omissis*] NBTS: (i) is already subject to its provisions and requirements, and (ii) already routinely processes special categories of personal data in the context of its activities for its existing blood and cornea transplant establishments, and should therefore already have well-established data handling processes and procedures in place (including measures for ensuring donor confidentiality etc.). [*omissis*] Note that any processing of donor data (specifically health or genetic information) may only be carried out by an individual who is subject to professional secrecy obligations (such as healthcare professionals). Moreover, as the set up and operation of the EBTC Project would constitute a new processing operation and would involve increased processing of special categories of personal data by NBTS, then a data DPIA would first need to be carried out (see article 35(3)(a), GDPR). Prior consultation with the Office of the Information and Data Protection Commissioner ("**IDPC**") may also be required if the outcome of the DPIA indicates that *residual risks* to the relevant individuals (e.g., donors) would still be present, notwithstanding the adoption of reasonable safeguards and mitigation measures.

		RECOMMENDATION: For information purposes, <u>but</u> we would recommend that NBTS augments and updates its data protection policies and processes in view of these proposed increased processing operations [*omissis*] From a regulatory perspective, the Tissues and Cells (Quality and Safety) Regulations requires that the informed consent of the prospective donor must be obtained prior to the procurement of that donor's cell and tissue proceeds. This same requirement also applies to blood donations as established by the Blood (Quality and Safety) Regulations. [*omissis*] [*omissis*] [*omissis*] [*omissis*] From a data retention perspective, NBTS would (in the context of the EBTC Project) need to take into account its record-keeping obligations under the Tissues and Cells (Quality and Safety) Regulations, which for instance mandate that donor records required for **traceability** must be kept for a minimum of 30 years (see regulation 6). [*omissis*] [*omissis*]
3.	MT: Data Protection Act (Chapter 586 of the Laws of Malta), and its subsidiary / secondary legislation.	**RELEVANCE**: Having replaced the previous act, the current Data Protection Act implements the GDPR and supplements it by introducing certain additional rules, albeit these are for the most part sector-specific provisions (e.g. insurance industry, education sector, journalism etc.). This is also done through a number of subsidiary legislation enacted under it. The Act also lays down the applicable procedure for appealing against decisions / fines by the IDPC. **BARRIER**: We do not perceive the Data Protection Act having much, if any, added impact on the EBTC Project beyond what the GDPR already requires. Most of these additional national rules found in the Data Protection Act, and its subsidiary legislation, are not particularly relevant to the EBTC Project. We are here assuming that donor information will not, by way of secondary processing, be used for research or statistical purposes.

		RECOMMENDATION: For information purposes.
4.	MT: Processing of Personal Data (Secondary Processing) (Health Sector) Regulations (Subsidiary Legislation 528.10 of the Laws of Malta)	**RELEVANCE**: These regulations establish the circumstances in which further processing of health data may take place in the health sector (termed "secondary processing" which is not linked to the primary purpose for which the data was originally collected). These circumstances / permitted purposes are exhaustively listed in its Regulation 3 and cover *inter alia*: (i) processing and analysis of records kept by all entities falling within the ambit of the health sector; (ii) the investigation and monitoring of health threats, which typically requires the processing of health record data for the protection of public health; (iii) access to health records for research activities. Access to health records for any such research purposes can only take place if the personal data has been anonymized. If it cannot be conducted using anonymized data, then the authorisation of the IDPC and the Health Ethics Committee within the Ministry for Health is required. Where granted, it must be conducted using pseudonymized data, and where this is not possible, appropriate measures must be taken to safeguard the rights and fundamental freedoms of the data subject by providing that data should be anonymized as soon as the research or the statistical study no longer require identifiable data. In all other cases, processing health records for any purpose other than those set out in these regulations requires the consent of the data subject concerned as provided for in the GDPR. **BARRIER**: No specific impact, based on our understanding of the stated aims and purposes of the EBTC Project. However, if NBTS does intend to undertake any secondary processing of donor records, it would need to ensure that its processing purpose: (i) falls within one of the permitted purposes set out in Regulation 3 of these regulations and (ii) is not barred by the Blood (Quality and Safety) Regulations and Tissues and Cells (Quality and Safety) Regulations, as applicable. **RECOMMENDATION**: For information purposes.
5.	Tissues and Cells (Quality and Safety) Regulations	**RELEVANCE**: These Regulations, which apply to cell and tissue establishments, contain certain data protection specific provisions. Its Regulation 10 states that an establishment must ensure that all data, including genetic information, collated by it within the scope of its regulatory / licensing obligations and to

	(Subsidiary Legislation 483.01 of the Laws of Malta)	which third parties have access, are rendered anonymous so that neither donors nor recipients remain identifiable. For that purpose, the establishment must ensure that: (i) data security measures are in place, as well as safeguards against any unauthorised data additions, deletions or modifications to donor files or deferral records and transfer of information; (ii) procedures are in place to resolve data discrepancies; (iii) no unauthorised disclosure of information occurs, whilst guaranteeing the traceability of donations; (iv) the identity of any recipient is not disclosed to the donor or his family and vice versa, without prejudice to any legislation in force on the conditions for disclosure, notably in the case of gametes donation; and (v) the information which is collected for the purposes of these regulations is held securely so that it is - (a) available for the purpose of, tracing donations; (b) not disclosed except in accordance with an order of a court, or as may otherwise be required by law or where made to an inspector appointed by the SPH. **BARRIER**: Whilst compliance must naturally be ensured, we do not envisage that these will have any new or extraordinary impact on NBTS, since broadly identical obligations should already be applicable and incumbent upon NBTS in the context of its blood and cornea transplant establishments. **RECOMMENDATION**: For information purposes only – compliance required.
6.	Human Organs, Tissues and Cell Donation Act (Chapter 558 of the Laws of Malta)	**RELEVANCE**: Article 5(3) of this Act states that the SPH is obliged to ensure that the processing of information contained in the National Human Organ and Tissue Donation Register is processed in compliance with the Data Protection Act. **BARRIER**: No particular impact as these requirements largely apply to the SPH. **RECOMMENDATION**: For information purposes - the SPH could potentially request the assistance of NBTS to help fulfil such obligations.

7.	Health Act (Chapter 528 of the Laws of Malta)	**RELEVANCE**: Part VIII of this Act enshrines a number of patient rights, including *inter alia* (a) the patient's right to access their medical records as long as such access is not detrimental to their overall well-being and (b) the patient's right to have their medical data processed in conformity with the Data Protection Act. **BARRIER**: No specific impact, as the NBTS is in any case already required to respect such rights by virtue of its obligations under *inter alia* the GDPR, Data Protection Act, the Blood (Quality and Safety) Regulations and the Tissues and Cells (Quality and Safety) Regulations (Subsidiary Legislation 483.01 of the Laws of Malta). **RECOMMENDATION**: For information purposes.

CATEGORY D: ETHICS AND PATIENT RIGHTS

	LEGISLATION	RELEVANCE, BARRIER AND RECOMMENDATION
1.	Human Organs, Tissues and Cell Donation Act (Chapter 558 of the Laws of Malta)	**RELEVANCE**: This Act regulates *inter alia* the national donor registration in Malta, stipulating that it is the responsibility of the SPH to maintain the National Human Organ and Tissue Donation Register and record in this register: (i) details of persons residing in Malta who wish to donate their organs, tissues or cells following their demise, (ii) details of persons residing in Malta who expressly declare that they do not wish to be a donor, (iii) any particular organ, tissue or cell a person chooses to donate or not donate. To be eligible for registration, the applicant must have mental competence and attained 16 years of age,[6] be making the request voluntarily out of his own free will, received adequate information and certified by a clinician of his mental competence and that he/she fully understands the nature and consequences of the donation. **Deceased adults who are NOT registered donors**: Next of kin **may** be approached by a transplant coordinator or a clinician to make a declaration whether they consent to the donation. If consent is given, the donation may take place and the person is deemed to be a registered donor. This procedure cannot be used if the deceased has registered to NOT be a donor. Particularly relevant to NBTS, this Act further provides that procurement organisations[7] and transplantation centres[8] must have in place a framework approved by the SPH to assess all potential live organ donors and to decide whether the transplant should be approved, based on the following criteria:

[6] Except in the case of donations/transplantations of regenerative hematopoietic stem cells for blood relatives.

[7] Defined as a health care establishment or team or unit of a hospital/person/other body with authorisation by the Superintendent which undertakes the procurement of organs.

[8] Defined as a health care establishment or team or unit of a hospital/person/other body with authorisation by the Superintendent to undertake the transplantation of organs, tissues and cells.

		(i) donations between blood relatives / donations between family members who are not blood relatives: an organ must be donated to an identified recipient; (ii) donations between non-related persons who have a "pre-existent close emotional link" (e.g: friends): the organ must be donated to a person with whom the donor has this close link for it to be accepted; (iii) donations between persons who are not related and who do not share a "pre-existent close emotional link": the principle of distributive justice shall be adopted by which a donated organ shall be allocated to a recipient according to his medical needs. The decision is to be taken by the SPH. Lastly, donor information contained in the national register must be processed according to data protection laws and can only be accessed for the purpose of determining whether the person is a registered donor or whether a person has declared that they do not wish to be a donor. This would therefore cover disclosure of donor information to procurement organisations and transplant centres. **BARRIER**: It will affect the manner in which these new proposed services within the EBTC Project can be conducted and provided, including in particular with regards to the approval of transplants. Furthermore, assuming the project proceeds, NBTS will have to develop a framework for assessing the eligibility / suitability of live donors and submit this to the SPH for its approval. [*omissis*] General compliance thereof would also be required and, in our opinion, an operational priority. NBTS would need to formulate a donor assessment framework for these added services, together with SOPs for its practical implementation, and submit these to the SPH for approval / sign-off.

2.	Health Act (Chapter 528 of the Laws of Malta)	**RELEVANCE**: **Part VII of the Act** establishes a number of patient rights [patient is defined in the Act as ***"a person who is receiving, or has received medical attention, care, or treatment, whether in a healthcare setting or otherwise"***] which can have an impact on the EBTC Project, namely as it establishes that every patient has the right to *inter alia* (i) receive information concerning his state of health, and the health services and treatments available; (ii) be provided in advance with clear information on the treatment options available, and to be involved in decisions/discussions about the treatment; (iii) be provided with access to his medical records and have his medical data processed according to the Data Protection Act (see Article 27 of the Act). Medical practitioners also required to certify that the patient has sufficient maturity and understanding to **consent to / refuse** medical attention or care or treatment (and if not the case, then the consent of the person having parental or other legal authority shall be required). **BARRIER**: Will govern the conduct of NBTS / its healthcare personnel in offering these new extended services. That being said, the patient rights set out in this Act should not in our opinion present any novel or extraordinary impact on NBTS given that it is already generally bound to comply with and respect these rights in the context of its blood and cornea transplant establishments. **RECOMMENDATION**: For information purposes.
3.	Charter of Patient's Rights and Responsibilities	**RELEVANCE**: Adds to the patient rights and responsibilities contained in the Health Act (as reviewed above) and highlights the level of service which a patient is entitled to expect and receive when utilising public health services The Charter is designed around eight core principles: (1) Health Protection; (2) Access; (3) Information; (4) Participation and Informed Consent; (5) Privacy and Confidentiality; (6) Dignity and Respect; (7) Safe Healthcare; and (8) Comments and Complaints. **BARRIER**: There is no envisaged added impact, as the principles contained in the Charter regulate the conduct of healthcare professionals and patients in a general manner, e.g., the patient's right to participate in immunisation programmes, adopt a healthy lifestyle etc. Highlighted below are some of the principles in the Charter which may be of relevance

		(as regards ethics and/or patient rights): (i) the patient's right to participate and discuss ethical matters that may arise in the course of one's care or treatment; (ii) the patient's right to have to have care/intervention started immediately in an emergency, (iii) the patient's right to **receive all information** associated with **risks and consequences** of treatment and prognosis; (iv) the patient's right to **refuse ANY treatment**, examination, test or screening procedure offered - refusal must be signed, documented and countersigned by a witness. **RECOMMENDATION**: For information purposes.

CATEGORY E: ENVIRONMENT

	LEGISLATION	RELEVANCE, BARRIER AND RECOMMENDATION
1.	EU: Regulation (EU) 2021/241 of the European Parliament and of the Council of 12 February 2021 establishing the Recovery and Resilience Facility EU: Regulation (EU) 2020/852 of the European Parliament and of the Council of 18 June 2020 on the establishment of a framework to facilitate sustainable investment, and amending Regulation (EU) 2019/2088 EU: Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives	**RELEVANCE**: According to the cost-benefit analysis carried out by RG Capital Advisors Limited and dated 19 November 2021, the Ministry for Health applied for a EUR 24.3 million grant under the EU's Recovery and Resilience Facility. We were also informed that one of the main principles underpinning the RRF is environmental considerations. This Regulation requires the recovery and resilience plan of each country to provide an explanation ensuring that the proposed measures, including the EBTC Project, cause no significant harm to environmental objectives (Article 18(4)(d) of the Regulation). This also ties in with the need to explain how Malta's proposed measures are expected to contribute to the green transition, which includes waste management (Article 18(4)(e) of the Regulation). The six environmental objectives which need to be taken into account for the purpose of determining the sustainability of the EBTC Project are: (a) climate change mitigation (b) climate change adaptation (c) sustainable use and protection of water and marine resources (d) transition to a circular economy (e) pollution prevention and control (f) protection and restoration of biodiversity and ecosystems. Indeed, 'significant harm' is defined as causing harm to any of the foregoing six environmental objectives (Article 17 of Regulation 2020/852). For instance, it causes significant harm to the circular economy, including waste prevention and recycling if it leads to significant inefficiencies in the use of materials, a significant increase in the generation or disposal of waste (with the exception of the incineration of non-recyclable hazardous waste) or if the long-term disposal of waste causes significant and long-term harm to the environment. The 'circular economy' is an economic system where the value of products is maintained for as long as possible and their environmental impact is reduced, minimising waste and release of hazardous substances (Article 2(9) of Regulation 2020/852), including through the application of the waste hierarchy i.e. the cycle of prevention, re-use, recycle, other recovery, and disposal (Article 4 of Directive 2008/98).

		Following the principles of the waste hierarchy is part and parcel of moving towards a circular economy. One of the aims stipulated by Directive 2008/98 is that at least 70% of constructions works (by weight) of the non-hazardous construction and demolition waste (including backfill material) generated on the construction site shall be prepared for re-use, recycling and other material recovery (Article 11(2)(b) of Directive 2008/98). We understand that the EU Commission is insisting on this requirement, hence its relevance. [*omissis*] [*omissis*] [*omissis*] [*omissis*] [*omissis*] [*omissis*]
2.	EU: Council Implementing Decision on the Approval of the Assessment of the Recovery and Resilience Plan for Malta EU: Annex to the Council Implementing Decision on the Approval of the Assessment of the Recovery and Resilience Plan for Malta	**RELEVANCE**: The Decision reiterates the 'do no significant harm' principle and the need for the EBTC Project to comply, as does the Annex. In particular, the Decision draws attention to the Construction and Demolition Waste Strategy for Malta and the avoidance of significant harm being inflicted by ensuring that: (a) no activity leads to a significant increase in waste disposal or disincentives to preparing for reuse or recycling and (b) the waste used for backfilling is suitable non-hazardous waste substituting non-waste materials and limited to that which is strictly necessary. The implementation of the Strategy requires: (a) the enactment of a new regulatory frameowork on construction and demolition waste (b) corresponding standards to reduce such waste in the first place and secondly to ensure that it is suitable for treatment in accordance with the waste hierarchy and (c) the recovery of such waste which is suitable for backfilling of quarries.

		More importantly, the Annex expressly states that the EBTC Project cannot fall foul of the 70% requirement explained above.[9] [*omissis*] [*omissis*]
3.	EU: Commission Notice: Technical Guidance on the Application of 'Do No Significant Harm' under the Recovery and Resilience Facility Regulation	**RELEVANCE**: This technical guidance is intended to assist national authorities in the preparation of the recovery and resilience plans and sets out practical examples for satisfying the 'do no significant harm' checklist. **BARRIER**: None envisaged since this is relevant at pre-recovery and resilience plan stage. **RECOMMENDATION**: For information purposes only.
4.	Blood (Quality and Safety) Regulations (Subsidiary Legislation 483.02 of the Laws of Malta)	**RELEVANCE**: These Regulations transpose a number of EU Directives as abovementioned into Maltese law for the purpose of ensuring the quality and safety of blood transfusions. Insofar as the environment is concerned, NBTS as a blood establishment is obliged to establish and maintain a quality system. An integral part of the quality system is the proper disposal of waste. NBTS must designate an area for the safe disposal of waste, disposal items used during the collection, testing and processing and for rejected blood and blood components. **BARRIER**: None envisaged, but NBTS will have to ensure compliance. **RECOMMENDATION**: None envisaged, but NBTS will have to ensure compliance.
5.	Human Tissues and Cells (Coding, Processing,	**RELEVANCE**: These Regulations transpose the Commission Directive 2006/86/EC which in itself implements the framework Council Directive 2004/23/EC on the quality and safety of human tissues and

[9] Council of the European Union, 'Annex to the Council Implementing Decision on the Approval of the Assessment of the Recovery and Resilience Plan for Malta' (28 September 2021) (p. 40).

	Preservation, Storage and Distribution) Regulations (Subsidiary Legislation 483.04 of the Laws of Malta)	cells. Schedule 1 to these Regulations require the tissues and cells establishment to have written policies and procedures for waste disposal. **BARRIER**: None envisaged, but NBTS will have to ensure compliance. **RECOMMENDATION**: For information purposes only, but NBTS will have to ensure compliance.
6.	Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on Waste and Repealing Certain Directives	**RELEVANCE**: This Directive serves as the lynchpin to the national laws on waste generally and specifically with regard to NBTS and its operations. Indeed, the NBTS policy on waste management makes several reference to this Directive and its content. This Directive achieves several objectives, including: (a) setting out the waste management hierarchy; (b) identifying hazardous waste in Annex 3 and by elimination, non-hazardous waste; (c) obliging Member States to have in place measures to prevent, re-use, recycle, and dispose of waste; (d) obliging Member States to ensure that waste management is carried out without endangering human health or harming the environment, particularly insofar as the production, collection, transportation, storage and treatment of hazardous waste is concerned; and (e) obliging Member States to impose the need for establishments to obtain a permit from the competent authority to carry out waste treatment. In Malta's case, the competent authority is the Environment and Resources Authority. Disposal of non-hazardous waste and recovery of waste may be exempted by Member States from the activities requiring a permit. 'treatment' is defined as 'recovery or disposal operations, including preparation prior to recovery or disposal'. The preparatory work carried out by the staff of NBTS in separating waste into distinct categories according to the operation procedures could potentially be classified as 'waste treatment'. **BARRIER**: None envisaged, since the NBTS Waste Management Policy already recognises and implements the waste management hierarchy and other principles set out in this Directive. However, we understand that NBTS has applied for the issue of the relevant permit by the Environment and Resources Authority for waste treatment specifically with regard to the EBTC Project. This permit should be in place prior to the commencement of operations.

		RECOMMENDATION: For information purposes only.
7.	MT: Waste Regulations (Subsidiary Legislation 549.63 of the Laws of Malta) EU: Commission Decision 2000/532/EC Establishing a List of Wastes	**RELEVANCE**: The Waste Regulations transpose the Waste Framework Directive, as well as the Commission Decision 2000/532/EC establishing a list of wastes. These Regulations impose the following obligations: (a) on any establishment which collects waste not to mix such waste with other waste or material with different properties;[10] (b) on the original waste producer[11] to ensure that the waste is managed by a person who is in possession of the required permit and in accordance with these Regulations, and to foot the bill for the waste management; (c) on the waste holder (including NBTS as the producer or the entity in temporary possession of the waste) to ensure that hazardous waste is securely packaged and labelled; (d) a prohibition on the mixing of hazardous waste either with other categories of hazardous waste or with other waste; (e) on any establishment to obtain a permit from the Environment and Resources Authority if that establishment intends to carry out waste treatment, including storage of waste pending any recovery or disposal operations. However, an important exception is made to the effect that this expressly excludes temporary storage of waste pending collection on the site where the waste is generated. This exception is reinforced in Schedule 4 of these Regulations which exempt establishments from the requirement to obtain a permit for the following activities: (a) disposal or recovery of their own non-hazardous waste on the site of generation and (b) preliminary storage of waste pending collection, at the place of production.

[10] 'collection' is defined as 'the gathering of waste, including the preliminary sorting and preliminary storage of waste for the purposes of transport to a waste treatment facility' (Regulation 4 of the Waste Regulations, Subsidiary Legislation 549.63 of the Laws of Malta).

[11] ibid, 'waste producer' is defined as anyone whose activities produce waste (original waste producer) or anyone who carries out pre-processing, mixing or other operations resulting in a change in the nature or composition of this waste.

		It is noteworthy that certain classes of healthcare waste (including waste pharmaceuticals and medicines) are expressly excluded from the permit requirement. However, these classes cater for small amounts of such waste as can be generated by households or private medical practices. **BARRIER**: NBTS must ensure compliance. **RECOMMENDATION**: NBTS must ensure compliance. [*omissis*]

CATEGORY F: [*omissis*]

CATEGORY G: OTHER LAWS

	LEGISLATION	RELEVANCE, BARRIER AND RECOMMENDATION
1.	[*omissis*]	[*omissis*]
2.	[*omissis*]	[*omissis*]
3.	[*omissis*]	[*omissis*]

SECTION 2: REVIEW OF THE RELEVANT NBTS POLICIES AND RECOMMENDATIONS

CATEGORY A: BLOOD, TISSUES AND CELLS

[*omissis*]

CATEGORY B: EQUALITY AND ACCESSIBILITY

[*omissis*]

CATEGORY C: DATA PROTECTION AND FREEDOM OF INFORMATION

[*omissis*]

CATEGORY E: ENVIRONMENT

[*omissis*]

5. Assumptions

5.1. For the purpose of providing this Report, we have assumed without further enquiry:

5.1.1. the authenticity, accuracy and completeness of the relevant NBTS Policies (and any facts, information or documents referred to therein) as well as the due execution, completeness and conformity to the originals of any NBTS Policies (and any documents referred to therein) that were submitted to us as copies. We have also assumed without further enquiry that no relevant fact, information, document or arrangement has been withheld from us;

5.1.2. that the relevant NBTS Policies (and any other information provided) were as current as possible at the time of their provision to us, that no material changes have occurred or were envisaged and, where relevant, have been renewed on the due date and, save where expressly and specifically brought to our attention, have not been terminated, supplemented or amended;

5.1.3. that all of the relevant NBTS Policies (including all staff guidelines referred to in them) have been implemented and are being observed and performed in accordance with their terms by NBTS and all of its staff;

5.1.4. that you are fully aware of and conversant with the NBTS Policies and their respective contents. Accordingly we have not repeated the contents, stipulations or facts as they may emerge from the NBTS Policies in this Report and reference should, therefore, be made to the NBTS Policies for completeness;

6. Limitations

6.1. Furthermore, our Report is subject to the following qualifications:

6.1.1. This Report is governed by and has been prepared pursuant to the provisions of the Public Contract;

6.1.2. This Report has been prepared strictly within the Scope and for the purpose stated herein and it shall not be used or relied upon for any other purpose nor shall it extend or apply by implication or otherwise to any other matter or transaction;

6.1.3. This Report supersedes earlier reports, presentations and statements, written or oral, prepared by us on this matter;

6.1.4. We accept no liability in respect of any matter not included within the purpose for which this Report has been prepared or otherwise outside the scope, parameters and limitations of this Report or the scope of our engagement;

6.1.5. This Report does not constitute an audit nor should it be regarded as, or relied upon as being equivalent to, a legal opinion concerning any matter referred to in this Report or any of the Documents, or treated as a substitute for specific legal advice concerning individual issues, circumstances, information, documents, events or concerns.

6.1.6. The accuracy of the Report necessarily depends on the documents reviewed and the replies to enquiries being true, complete, accurate and not misleading, and on the documents reviewed being legally binding and effective, all of which we have assumed to be the case.

6.1.7. This Report refers only to the position as at the Report Date. We do not assume any obligation to advise any person entitled to rely on the Report of any change in, or in the interpretation of, the Relevant Legislation subsequent to the Report Date or of any, knowledge we might obtain after the Report Date of matters which render the Report inaccurate, incomplete or misleading as at the Report Date and which, had we known of them at the Report Date, would have led to material changes being made to the content of the Report and accordingly we accept no responsibility to update this Report in light of any of the above.

6.1.8. This Report does not constitute in any manner a recommendation, approval, invitation, incentive, inducement, or a solicitation to set-up or implement the EBTC Project or grant any waivers or to enter into and perform any activity or transaction.

7. Qualifications

7.1. Furthermore, our Report is subject to the following qualifications:

7.1.1. The purpose of the Report is solely to set out and draw your attention to the legal matters which may be relevant to you in the development and functioning of the EBTC Project. We have endeavoured to include all material relevant to the EBTC Project in our Report.

7.1.2. In conducting our review and identifying documents to be reviewed and matters for inclusion in our Report, we have exercised our judgement on a "no liability" basis considering what we believe is likely to be materially relevant to you. Specifically, in reviewing the NBTS Policies, we have only perused those policies which relate to the sections which fall within the scope of our Report and such other policies which we have deemed relevant to peruse in order to identify any potential non-compliance with the existing and in-draft national and EU legal framework. The selected policies were expressly approved by you by means of an e-mail dated 25 May 2022.

7.1.3. In rendering the Report, we have relied on and/or reviewed (as appropriate), and the Report is itself based upon, solely and exclusively: (i) the Relevant Legislation (ii) the NBTS Policies supplied to us by you in connection with the Public Contract and (iii) the written communications, statements, notices or information provided to us by you in particular cases. No on-site inquiry or verification has been made by us.

7.1.4. Unless expressly indicated in our Report, we did not perform any independent verification of the information that was made available to us.

7.1.5. In our Report, we have not expressed any opinion on the law of any jurisdiction other than the laws of Malta.

7.1.6. Based on the information provided to us, we understand that the purpose of the EBTC Project is to explore the set-up and functioning in Malta of a tissue and cell establishment, we have therefore not reviewed local or EU legislation pertaining to organs and organ transplants. This includes, by way of example, the Organ Transplants (Quality and Safety) Regulations

(Subsidiary Legislation 483.06 of the Laws of Malta) and the Information Procedures for the Exchange, between Member States, of Human Organs Intended for Transplantation Regulations (Subsidiary Legislation 483.07 of the Laws of Malta).

7.1.7. The EBTC Project (including its make-up and the services planned to be introduced by it) are as described in the document titled "*EBTC Medical Brief by Dr. George Galea*" (the "Medical Brief") and, save only for any further information provided to us in writing, there are no material changes or developments currently contemplated or envisaged in relation to this EBTC Project. Furthermore, the Report does not take into consideration any other services or methods of service delivery beyond those set out in the Medical Brief. Provided, however, we have been made aware that the EBTC Project could potentially in future develop to also include the following additional services: (a) the exportation of blood and blood components, tissues and cells; and (b) the provision of starting materials for medicine including advanced therapy medicinal products. However, as such matters were not included in the Medical Brief and, at this stage, the provision of such additional services is only a possible future development, they have – with the agreement of the Contracting Authority - been omitted from our assessment and this Report. We have therefore not reviewed local or EU legislation pertaining to such matters. This includes, by way of example, the Medicines Act (Chapter 458 of the Laws of Malta), Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, Regulation (EU) 2017/746 of the European Parliament and of the Council on in vitro diagnostic medical devices, and Regulation (EC) No 1394/2007 of the European Parliament and of the Council on advanced therapy medicinal products.

7.1.8. We closed our Preliminary Report on 6 June 2022 and have closed our Report as of 14 July 2022 (the "**Report Date**") and have not updated the Report with new legal developments which may have arisen after this date. However, known upcoming legislation and/or legislative amendments have been taken into consideration and are reflected in this Report.

7.1.9. In the Report, we have reported only on legal issues and have done this exclusively on the basis of the Relevant Legislation, including for the avoidance of doubt any relevant regulations and directives issued by the European Union, as at the Report Date.

7.1.10. It has not been possible to assess whether the NBTS Policies provided to us were complete or whether they comprised or not the totality of documents needed for us to carry out a proper and exhaustive analysis. Accordingly, Ganado Advocates do not assume any responsibility in this respect.

7.1.11. Some of the NBTS Policies supplied to us may include or contain confidentiality undertakings binding upon you and/or other parties. We are not aware, and we have made no enquiry, whether the NBTS Policies have been made available to us in conformity with or in breach of these confidentiality undertakings.

7.1.12. Any opinion of law given by us in respect of a particular fact, issue or set of circumstances should not be deemed or construed to constitute an assurance or guarantee that no claim or pretension or proceedings of any kind will be made, initiated or taken by any person or entity thereon whether now or at any time in the future.

ANNEX I – LIST OF REVIEWED DOCUMENTS

LEGISLATION – EU

1. Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC;
2. Commission Directive 2004/33/EC of 22 March 2004 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards certain technical requirements for blood and blood components;
3. Commission Implementing Directive 2011/38/EU of 11 April 2011 amending Annex V to Directive 2004/33/EC with regards to maximum pH values for platelets concentrates at the end of the shelf life;
4. Commission Directive 2014/110/EU of 17 December 2014 amending Directive 2004/33/EC as regards temporary deferral criteria for donors of allogeneic blood donations;
5. Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells;
6. Commission Directive 2005/62/EC of 30 September 2005 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards Community standards and specifications relating to a quality system for blood establishments;
7. Commission Directive 2016/1214 of 25 July 2016 amending Directive 2005/62/EC as regards quality system standards and specifications for blood establishments;
8. Commission Directive 2005/61/EC of 30 September 2005 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards traceability requirements and notification of serious adverse reactions and events;
9. Commission Directive 2009/135/EC of 3 November 2009 allowing temporary derogations to certain eligibility criteria for whole blood and blood components donors laid down in Annex III to Directive 2004/33/EC in the context of a risk of shortage caused by the Influenza A(H1N1) pandemic;
10. Stakeholder Workshop with Blood Competent Authorities on ‘Regulating for Sufficiency – Blood and Plasma’ held on 4 May 2021;
11. Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells;
12. Commission Directive 2006/17/EC of 8 February 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells;
13. Commission Directive 2012/39/EU of 26 November 2012 amending Directive 2006/17/EC as regards certain technical requirements for the testing of human tissues and cells;

14. Commission Directive 2006/86/EC of 24 October 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells;
15. Commission Directive (EU) 2015/565 of 8 April 2015 amending Directive 2006/86/EC as regards certain technical requirements for the coding of human tissues and cells;
16. Commission Directive (EU) 2015/566 of 8 April 2015 implementing Directive 2004/23/EC as regards the procedures for verifying the equivalent standards of quality and safety of imported tissues and cells;
17. Commission Decision of 3 August 2010 establishing guidelines concerning the conditions of inspections and control measures, and on the training and qualification of officials, in the field of human tissues and cells provided for in Directive 2004/23/EC of the European Parliament and of the Council;
18. Commission Decision of 3 July 2015 establishing a model for agreements between the Commission and relevant organisations on the provision of product codes for use in the Single European Code;
19. Council Directive 2004/113/EC implementing the principle of equal treatment between men and women in the access to and supply of goods and services;
20. Council Directive 2000/43/EC implementing the principle of equal treatment between persons irrespective of racial origin;
21. Charter of Fundamental Rights of the European Union;
22. European Convention on Human Rights;
23. General Data Protection Regulation (EU Regulation 2016/679);
24. Charter of Patient's Rights and Responsibilities;
25. Regulation (EU) 2021/241 of the European Parliament and of the Council of 12 February 2021 establishing the Recovery and Resilience Facility;
26. Regulation (EU) 2020/852 of the European Parliament and of the Council of 18 June 2020 on the establishment of a framework to facilitate sustainable investment, and amending Regulation (EU) 2019/2088;
27. Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives;
28. Council Implementing Decision on the Approval of the Assessment of the Recovery and Resilience Plan for Malta;
29. Annex to the Council Implementing Decision on the Approval of the Assessment of the Recovery and Resilience Plan for Malta;
30. Commission Notice: Technical Guidance on the Application of 'Do No Significant Harm' under the Recovery and Resilience Facility Regulation;
31. Commission Decision 2000/532/EC Establishing a List of Wastes; and
32. Treaty on the Functioning of the European Union.

LEGISLATION – MALTA

1. Human Blood and Transplants Act (Chapter 483 of the Laws of Malta);
2. Human Blood and Transplants (Fees) Regulations (Subsidiary Legislation 483.09 of the Laws of Malta);
3. Blood (Quality and Safety) Regulations (Subsidiary Legislation 483.02 of the Laws of Malta);
4. Traceability Requirements and Notification of Serious Adverse Reactions and Events Regulations (Subsidiary Legislation 483.03 of the Laws of Malta);
5. Blood Supply (Temporary Derogations to Eligibility Criteria) Regulations (Subsidiary Legislation 483.05 of the Laws of Malta);
6. Tissues and Cells (Quality and Safety) Regulations (Subsidiary Legislation 483.01 of the Laws of Malta);
7. Equivalent Standards of Quality and Safety of Imported Tissues and Cells Regulations (S.L. 483.08 of the Laws of Malta);
8. Human Tissues and Cells (Coding, Processing, Preservation, Storage and Distribution) Regulations (Subsidiary Legislation 483.04 of the Laws of Malta);
9. Human Organs, Tissues and Cell Donation Act (Chapter 558 of the Laws of Malta);
10. Access to Goods and Services and their Supply (Equal Treatment) Regulations (Subsidiary Legislation 456.01 of the Laws of Malta);
11. Equal Treatment of Persons Order (Subsidiary Legislation 460.15 of the Laws of Malta) ;
12. Bill entitled the 'Equality Act, 2019' (not yet law);
13. Health Act (Chapter 528 of the Laws of Malta);
14. Equality for Men and Women Act (Chapter 456 of the Laws of Malta);
15. Employment and Industrial Relations Act (Chapter 452 of the Laws of Malta);
16. Freedom of Information Act (Chapter 496 of the Laws of Malta);
17. Data Protection Act (Chapter 586 of the Laws of Malta), and its subsidiary / secondary legislation;
18. Processing of Personal Data (Secondary Processing) (Health Sector) Regulations (Subsidiary Legislation 528.10 of the Laws of Malta);
19. Health Act (Chapter 528 of the Laws of Malta);
20. Waste Regulations (Subsidiary Legislation 549.63 of the Laws of Malta);
21. [*omissis*]

NBTS POLICIES

[*omissis*]