

**TENDER FOR THE SUPPLY OF SERVICES FOR CARRYING OUT A LEGAL REVIEW OF LEGISLATION THAT MAY IMPACT  
THE NEW ESTABLISHMENT OF BLOOD, TISSUES, AND CELLS (EBTC)**

**FIRST PHASE REPORT**

***Project Synopsis***

We understand that the National Blood Transfusion Service (the '**NBTS**') shall shortly proceed with the design and build of the New Establishment for Blood Tissues and Cells (the '**EBTC Project**'). The new establishment shall continue to provide the current blood transfusion services together with additional facilities for HLA typing, processing and storage of plasma for fractionation, autologous stem cell banking for transplantation for oncology patients, cornea banking (warm banking), amnion and bone banking. Other tissues may be eventually considered including skin and tendons. The scope will also extend to cellular therapies.

We understand that the purpose of our engagement covers: (a) the identification of the legislation pertinent to this new establishment and how such legislation may affect the EBTC Project (b) a review of the current policies and practices of the NBTS to ensure that these are in compliance with the said pertinent legislation (c) identification of the potential issues and bottlenecks arising from either the legislation or the current policies and practices of the NBTS and which may affect the EBTC Project and (d) recommend amendments to legislation or policies and practices to overcome the potential issues and bottlenecks.

The scope of this First Phase Report is limited to (a) the identification of the legislation pertinent to this new establishment and how such legislation may affect the EBTC Project and the identification of the policies and practices of NBTS to be reviewed in (b) which review shall form part of the Second Phase Report.

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**EBTC IDENTIFICATION OF LAWS**

**CATEGORY A: BLOOD AND TISSUE LEGISLATION**

<u>Field of Law</u>	<u>Legislation</u>	<u>Relevance of Legislation</u>	<u>Impact Envisaged</u>
Blood and Tissue Legislation	Human Blood and Transplants Act (Chapter 483 of the Laws of Malta)	Establishes the Licensing Authority and lays down the activities requiring the grant of a licence.	The NBTS needs to apply for and obtain a licence to carry out certain activities in relation to the EBTC Project.
Blood and Tissue Legislation	Tissues and Cells (Quality and Safety) Regulations (Subsidiary Legislation 483.01 of the Laws of Malta)	Establishes and/or regulates: (a) the need for the appointment of a designated person within the tissues and cells establishment and their respective responsibilities (b) the responsibilities of the tissues and cells establishment (c) the need for a quality management system (d) requirements for the procurement of tissues and cells and (e) the recruitment and medical selection of donors.  Schedules I to IV are also important insofar as donors are concerned. In particular, Schedule II and Schedule III mandate the selection criteria and laboratory tests while Schedule IV provides the	We will have to review the quality management system and standard operating procedures of the NBTS to: (a) ensure compliance with these Regulations and (b) assess the need for amendments in view of the EBTC Project.  The Regulations may need to be amended to reflect the new services which the NBTS plans to introduce.

		<p>framework for the selection criteria and laboratory tests for donors of reproductive cells specifically. Schedule V in turn establishes the procedure for the procurement and reception of donated cells and tissues at the establishment.</p>	
<p>Blood and Tissue Legislation</p>	<p>Blood (Quality and Safety) Regulations (Subsidiary Legislation 483.02 of the Laws of Malta)</p>	<p>Establishes and/or regulates: (a) the need for the appointment of a designated person within the blood establishment (already in place) (b) the responsibilities of the blood establishment (c) labelling and traceability of blood and blood components (d) the need for a quality management system.</p> <p>The Schedules are also of relevance, in particular:</p> <p>(a) Schedule III on labelling requirements (with exceptions for plasma intended for fractionation)  (b) Schedule IV on basic testing requirements (with exceptions for plasma intended for fractionation)  (c) Schedule VII on requirements for storage, transport distribution of blood and blood components and (d) Schedule VIII on quality and safety requirements and (e) Schedule IX on the quality system standards and specifications.</p>	<p>Amongst other things, this will govern the procedure to be used in the shift from the importation of non-labile blood products to the locally-based plasma programme for the collection of plasma as a source material.</p>

<p>Blood and Tissue Legislation</p>	<p>Traceability Requirements and Notification of Serious Adverse Reactions and Events Regulations (Subsidiary Legislation 483.03 of the Laws of Malta)</p>	<p>Governs: (a) the requirement for blood and blood components to be traceable from donor to recipient (b) the procedure to be followed in case of serious adverse events and (c) the procedure to be followed in case of serious adverse reactions.</p> <p>These are requirements mandated by EU Law (specifically Directive 2005/61/EC and Directive 2002/98/EC).</p>	<p>Under the auspices of the Commission Work Programme 2021, the EU Plans to: (a) render the directives more malleable to scientific and technological progress (e.g. better donor tests and new processing methods) and (b) address the lessons learnt from the COVID-19 pandemic.</p> <p>[omissis].</p>
<p>Blood and Tissue Legislation</p>	<p>Human Tissues and Cells (Coding, Processing, Preservation, Storage and Distribution) Regulations (Subsidiary Legislation 483.04 of the Laws of Malta)</p>	<p>Establishes: (a) the need for a tissue establishment to follow the Schedule I procedure to be accredited and licensed as a tissue establishment (b) traceability requirements for tissues and cells (c) the procedure to be followed in the case of serious adverse events or serious adverse reactions and (d) the Single European Code requirement and (e) the procedure to be followed for processing tissues and cells.</p>	<p>NBTS may need to obtain accreditation and licensing to carry out the new services envisaged under the EBTC Project.</p>

<p>Blood and Tissue Legislation</p>	<p>Equivalent Standards of Quality and Safety of Imported Tissues and Cells Regulations (Subsidiary Legislation 483.08 of the Laws of Malta)</p>	<p>Regulates the importation of tissues and cells, and manufactured products derived from tissues and cells, for human application.</p>	<p>We note that the EBTC Project may be used as a holding bank of imported tissues and cells. [omissis]</p> <p>Under the auspices of the Commission Work Programme 2021, the EU Plans to: (a) render the directives more malleable to scientific and technological progress (e.g. better donor tests and new processing methods) and (b) address the lessons learnt from the COVID-19 pandemic.</p> <p>According to our research, the Impact Assessment has been published and the EU Commission is in the process of drafting a legislative proposal. We will keep an eye out for publication to determine the impact envisaged, if any.</p>
<p>Blood and Tissue Legislation</p>	<p>Human Blood and Transplants (Fees) Regulations (Subsidiary Legislation 483.09 of the Laws of Malta)</p>	<p>Establishes the fees payable for the issue of or substantial change to a licence issued under the main Human Blood and Transplants Act.</p>	<p>The new services may be classified as a 'substantial change' in terms of the main Act and trigger the need for payment of the relative fees.</p>

			<p>The fees are applicable to licensing requests (and to the annual renewal of such) and applications for approvals to substantial changes, ranging from EUR 300 to EUR 10,000. These may be waived or reduced by the Licensing Authority at its discretion; <i>[omissis]</i></p>
<p>Blood and Tissue Legislation</p>	<p>Human Organs, Tissues and Cell Donation Act (Chapter 558 of the Laws of Malta)</p>	<p>Establishes the National Human Organ and Tissue Donation Register for the donation of organs, tissues or cells.</p>	<p>No impact is envisaged since we have been informed that the bone-marrow donor registry needs to be independent and separate to the already existing National Organ Donation Register.</p> <p><i>[omissis]</i></p>

**EBTC IDENTIFICATION OF LAWS**

**CATEGORY B: EQUALITY AND ACCESSIBILITY LEGISLATION**

Equality and Accessibility	Access to Goods and Services and their Supply (Equal Treatment) Regulations (Subsidiary Legislation 456.01 of the Laws of Malta)	Lays down a framework for combating discrimination based on gender in the access to and supply of goods and services.	NBTS will have to ensure compliance.
Equality and Accessibility	Equal Treatment of Persons Order (Subsidiary Legislation 460.15 of the Laws of Malta)	Article 4 of this Order prohibits discrimination in relation to healthcare.	NBTS will have to ensure compliance.
Equality and Accessibility	Bill entitled the 'Equality Act, 2019' (not yet law).	Reiterates the prohibition against discrimination in relation to healthcare offered to the general public in Article 7 and 8, specifically:  <i>'discrimination in the access to goods and services, be they of a commercial nature or</i>	NBTS will have to ensure compliance if this comes into force. If the Bill does not come into force, NBTS may comply with same as a matter of best practice.



		<p><i>otherwise, shall include less favourable treatment in:</i></p> <p><i>(b) the provision of health and medical care and other medical services.</i></p>	
Equality and Accessibility	<p>(a) Charter of Fundamental Rights of the European Union</p> <p>(b) European Convention on Human Rights</p>	<p>Title III of this Charter establishes a general prohibition against discrimination.</p> <p>Article 14 of this Convention lays down a general prohibition against discrimination.</p>	No barrier envisaged.
Equality and Accessibility	<p>Council Directive 2000/43/EC of 29 June 2000 implementing the principle of equal treatment between persons irrespective of racial origin</p>	<p>Prohibits discrimination based on racial or ethnic origin including in the field of healthcare and general access to and supply of goods and services.</p>	No barrier envisaged.
Equality and Accessibility	<p>Directive (EU) 2019/882 of the European Parliament and of the</p>	<p>Establishes requirements relation to the provision of (particularly virtual or electronic) services to</p>	<p>NBTS will have to ensure that the new services are equally accessible to all sectors of the Maltese population,</p>

	Council of 17 April 2019 on the accessibility requirements for products and services (not yet law)	maximise their foreseeable use by persons with disabilities.	including in particular: (a) elderly persons and (b) individuals with disabilities.  The digitisation process will have to take this Directive into account.
Equality and Accessibility	Health Act (Chapter 528 of the Laws of Malta)	The <i>raison d'être</i> of this Act is to establish a health care system based on accessibility by regulating the entitlement to the healthcare services in Malta.	Not applicable.

**EBTC IDENTIFICATION OF LAWS**

**CATEGORY C: DATA PROTECTION AND FREEDOM OF INFORMATION LEGISLATION**

Data Protection and Freedom of Information	Tissues and Cells (Quality and Safety) Regulations (Subsidiary Legislation 483.01 of the Laws of Malta)	Regulation 10 lays down the requirement for data protection and confidentiality as well as the manner in which data collected for the purposes of any activities regulated by this Act may be disclosed. This is without prejudice to any other law in force on the conditions for disclosure e.g. donation of reproductive cells.	NBTS will have to ensure compliance.
Data Protection and Freedom of Information	Blood (Quality and Safety) Regulations (Subsidiary Legislation 483.02 of the Laws of Malta)	Regulation 9 lays down the requirement for data protection and confidentiality as well as the manner in which information collected for the purposes of any activities regulated by this Act may be disclosed.	NBTS will have to ensure compliance.
Data Protection and Freedom of Information	Human Organs, Tissues and Cell Donation Act (Chapter 558 of the Laws of Malta)	Article 5(3) of this Act states that the Superintendent of Public Health is obliged to ensure that the processing of information contained in the National Human Organ and	NBTS will have to ensure compliance.

		Tissue Donation Register is processed in compliance with the Data Protection Act.	
Data Protection and Freedom of Information	Data Protection Act (Chapter 586 of the Laws of Malta)	<p>Applies to the processing of personal data which forms part or is intended to form part of a filing system, including by automated means.</p> <p>‘personal data’ means any information relating to an identified or identifiable natural person (the data subject).</p> <p>‘data concerning health’ and ‘genetic data’ are each considered a special category of personal data and thus their processing is subject to additional conditions and restrictions.</p>	NBTS will have to ensure compliance.
Data Protection and Freedom of Information	General Data Protection Regulation (EU Regulation 2016/679)	<p>Applies to the processing of personal data which forms part or is intended to form part of a filing system, including by automated means.</p> <p>‘personal data’ means any information relating to an identified or identifiable natural person (the data subject).</p>	NBTS will have to ensure compliance.

Data Protection and Freedom of Information	Freedom of Information Act (Chapter 496 of the Laws of Malta)	Regulates the manner in which an application may request a public authority to disclose information.  [omissis]	NBTS will have to ensure compliance.
Data Protection and Freedom of Information	Health Act (Chapter 528 of the Laws of Malta)	Safeguards: (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.	NBTS will have to ensure compliance.
Data Protection and Freedom of Information	Processing of Personal Data (Secondary Processing) (Health Sector) Regulations	Regulates the further processing of personal data in the health sector which is not linked to the primary purpose for which the data was originally collected.	NBTS will have to ensure compliance.

**EBTC IDENTIFICATION OF LAWS**

**CATEGORY D: ETHICS AND PATIENT RIGHTS LEGISLATION**

Ethics and Patient Rights	Human Organs, Tissues and Cell Donation Act (Chapter 558 of the Laws of Malta)	The Act (a) regulates the manner in which a donation of tissues and cells by a deceased person takes place and (b) protects the right of a deceased person who has expressly declares their wish not to donate any tissues or cells.	[omissis]
Ethics and Patient Rights	Health Act (Chapter 528 of the Laws of Malta)	Part VIII of this Act establishes a number of patient rights.	No barrier envisaged as these principles regulate the conduct of healthcare professionals and patients generally.
Ethics and Patient Rights	Charter of Patient's Rights and Responsibilities	Establishes and complements the patient rights and responsibilities laid down in the Health Act on the basis of eight principles: (a) health protection (b) access (c) information (d) participation and informed consent (e) privacy and confidentiality (f) dignity and respect (g) safe healthcare and (i) comments and complaints.	No barrier envisaged as these principles regulate the conduct of healthcare professionals and patients generally.

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**CATEGORY E: ENVIRONMENT LEGISLATION**

Environment	Annex to the Proposal for a Council Implementing Decision	[omissis]	NBTS, and its contractors, will have to ensure compliance.
Environment	Regulation (EU) 2021/241 Establishing the Recovery and Resilience Facility	Establishes the 'do no significant harm' requirement for any projects benefitting from the facility.	NBTS will have to ensure compliance.
Environment	[omissis]	[omissis]	[omissis]
Environment	[omissis]	[omissis]	[omissis]
Environment	Environmental Management Construction Site Regulations (Subsidiary	Establishes numerous protocols to be followed in the construction process.	No barrier envisaged, NBTS, and its contractors, will have to ensure compliance.

	Legislation 552.09 of the Laws of Malta)		
Environment	Blood (Quality and Safety) Regulations (Subsidiary Legislation 483.02 of the Laws of Malta)	Mandates the designation of an area for the safe disposal of waste and other items used in the processing of blood and blood components.	[omissis]
Environment	Human Tissues and Cells (Coding, Processing, Preservation, Storage and Distribution) Regulations	Establishes the need for the tissue establishment to have written policies and procedures for waste disposal.	[omissis]



**EBTC IDENTIFICATION OF LAWS**

**CATEGORY F: [omissis]**

**EBTC IDENTIFICATION OF LAWS**

**CATEGORY G: OTHER AREAS OF LAW**

[omissis]	[omissis]	[omissis]	[omissis]
[omissis]	[omissis]	[omissis]	[omissis]
[omissis]	[omissis]	[omissis]	[omissis]
[omissis]	[omissis]	[omissis]	[omissis]