EUROPEAN BLOOD ALLIANCE

EBA DPO/Privacy Officers group paper on the 'right to erasure' or Right to be Forgotten under the General Data Protection Legislation

1. Purpose

The EBA DPO/Privacy working group was formed in early 2018 in response to the new Europe wide data protection legislation the General Data Protection Regulation (GDPR) EU 679/2016 coming into force in May of that year. One of the aims of the group is to conduct research, provide opinions, guidance and ultimately position papers in relation to data protection topics insofar as they apply in relation to blood transfusion.

The specific purpose of this paper relates to the right to be forgotten, it aims to provide guidance on how to interpret this right under data protection legislation in the blood transfusion context. Specifically the paper relates to blood components, tissues and cells, including from cord blood and bone marrow. While organs are outside the remit of the group and the EBA, it is acknowledged that there are many points of similarity both in terms of the governing legislation and its objectives, for example traceability. Much of the guidance provided here could therefore be of some use in that context also.

2. Right to be Forgotten legal framework

Under the new GDPR legislation which applies across all EU member states, individuals have a number of rights in relation to the way organisations process their personal data. These rights are defined in Chapter III of the legislation and include the right to access their data, the right to rectify incorrect data, and the right to erasure.

Article 17(1) of the GDPR relates specifically to this right to erasure or 'right to be forgotten'. It specifies that:

The data subject shall have the right to obtain from the controller the erasure of personal data concerning him or her without undue delay and the controller shall have the obligation to erase personal data without undue delay where one of the following grounds applies:

(a) the personal data are no longer necessary in relation to the purposes for which they were collected or otherwise processed;

(b) the data subject withdraws consent on which the processing is based according to point (a) of Article 6(1), or point (a) of Article 9(2), and where there is no other legal ground for the processing;

(c) the data subject objects to the processing pursuant to Article 21(1) and there are no overriding legitimate grounds for the processing, or the data subject objects to the processing pursuant to Article 21(2);

(d) the personal data have been unlawfully processed;

(e) the personal data have to be erased for compliance with a legal obligation in Union or Member State law to which the controller is subject;

(f) the personal data have been collected in relation to the offer of information society services referred to in Article 8(1).

However it also allows for certain circumstances in which the right to be forgotten is restricted as specified in Art 17 (3) as follows:

a) for exercising the right of freedom of expression and information;

b) for compliance with a legal obligation which requires processing by Union or Member State law to which the controller is subject or for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller;

c) for reasons of public interest in the area of public health in accordance with points (h) and (i) of Article 9(2) as well as Article 9(3);

d) for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89(1) in so far as the right referred to in paragraph 1 is likely to render impossible or seriously impair the achievement of the objectives of that processing; or (e) for the establishment, exercise or defence of legal claims.

3. Definitions

3.1 General definitions

The following general definitions will apply throughout this paper:

'Blood Establishment'(BE) - 'shall mean any structure or body that is responsible for any aspect of the collection and testing of human blood or blood components, whatever their intended purpose, and

their processing, storage, and distribution when intended for transfusion. This does not include hospital blood banks'[1]

Blood 'traceability'- ' means the ability to trace each individual unit of blood or blood component derived thereof from the donor to its final destination, whether this is a recipient, a manufacturer of medicinal products or disposal, and vice versa'[2]

*Tissue 'traceability'- '*means the ability to locate and identify the tissue/cell during any step from procurement, through processing, testing and storage, to distribution to the recipient or disposal, which also implies the ability to identify the donor and the tissue establishment or the manufacturing facility receiving, processing or storing the tissue/cells, and the ability to identify the recipient(s) at the medical facility/facilities applying the tissue/cells to the recipient(s); traceability also covers the ability to locate and identify all relevant data relating to products and materials coming into contact with those tissues/cells;[3]

'Donation' – for the purposes of this document donation is taken to mean any attempt to put a needle into the arm of the donor whether it results in a successful donation or not

'Registration' – for the purposes of this document references to registration should be understood in the following two ways

a) Registration is used to mean the donor has registered their details/registered their interest to donate but are yet to attend a blood donation clinic to make a donation. Such donors, often referred to as 'prospect' donors, may have a record created on the BE's systems.
b) Session registration is used to mean the step/process at the donation clinic where the donor's attendance is registered.

3.2 GDPR definitions

As per Article 4 of the GDPR the following definitions apply:

'personal data' means any information relating to an identified or identifiable natural person ('data subject'); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person; (2)

'processing' means any operation or set of operations which is performed on personal data or on sets of personal data, whether or not by automated means, such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission,

[1] Art 3(e) directive 2002/98/EC
[2] Art 1(a) 2005/61/EC
[3] Art 1 (g) 2006/86/EC

dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction;

'controller' means the natural or legal person, public authority, agency or other body which, alone or jointly with others, determines the purposes and means of the processing of personal data; where the purposes and means of such processing are determined by Union or Member State law, the controller or the specific criteria for its nomination may be provided for by Union or Member State law;

'processor' means a natural or legal person, public authority, agency or other body which processes personal data on behalf of the controller;

This list is not exhaustive but rather presents the most relevant definitions for ease of reading the document. In all cases where a term from the GDPR is used the standard definition as per the legislation should be taken to apply.

4. Scope

The scope of this document will include donors for whom the blood establishment (BE) acts as a data controller, patients, where the BE may act as a controller/joint controller or a processor, and BE staff insofar as an exercise of this right in the staff context could have an impact on processes which relate to donors or patients, i.e. where the member of staff is directly involved in the chain of activities from donation to transfusion.

Where the BE is acting as a data controller it is solely responsible for facilitating the exercise of donors rights under the legislation insofar as it is compatible with other legislation to which it is subject. Where it is acting as joint controller in relation to patient data for example, it will be jointly responsible for facilitating those rights insofar as it relates to the personal data collected and further generated by the BE.

Where the BE is acting purely as a data processor however, for example in the scenario where it is providing reference testing services for patients in a hospital, facilitating the patients' rights under the GDPR legislation is primarily the responsibility of the hospital or referring institution as the data controller. The BE will support the exercise of these patient rights in line with the instructions of the data controlling hospital/institution, according to any agreements in place and insofar as it is compatible with other legislation to which it is subject.

In each scenario, the BE is subject to the same traceability and retention requirements under the Blood Directive (2002/98/EC) as Art 2(1) states that the 'blood directive shall apply to the collection and testing of human blood and blood components, whatever their intended purpose, and to their processing, storage, and distribution when intended for distribution.'

5. Rationale and appropriate legislation

The GDPR allows for exemptions to the right to be forgotten in certain specific instances as mentioned in section 2 above. In particular Article 17 3(b) states that the right to be forgotten may be refused where the data is being processed *'for compliance with a legal obligation which requires processing by Union or Member State law to which the controller is subject or for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller; '*

Blood and Tissue establishments collect and process data for reasons of public interest and generally under official authority. They are subject to the following directives and associated national legislation (refer also to Appendix 1 for more detail) which put requirements on them in relation to the retention of traceability data.

Directive	**Requirement**
1. Blood Directive Directive 2002/98/EC: ~ Setting the 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	'data needed for full traceability in accordance with this Article shall be kept for at least 30 years' (Article 14(3)). 'Member states shall take all necessary measures to ensure that blood establishments maintain records of the information required in Annexes II and IV and under Article 29 (b), (c) and (d). The records shall be kept for a minimum of 15 years' (Article 13(1))
2. Traceability Requirements and Notification of SAE/SAR's Blood Directive 2005/61/EC: ~ 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	'Member States shall ensure that blood establishments, hospital blood banks, or facilities retain the data set out in Annex I for at least 30 years in an appropriate and readable storage medium in order to ensure traceability' (Article 4)
3. Tissue directive Directive 2004/23/EC ~ Setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells	' data required for full traceability shall be kept for a minimum of 30 years after clinical use.' (Article 8(4))
4. Traceability Requirements and Notification of SAE/SAR's Tissue	' Tissue establishments and organisations responsible for human application shall retain

Directive 2006/86/EC:~ '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'	the data set out in Annex VI for at least 30 years, in an appropriate and readable storage medium.' (Article 9(2))

The same retention and traceability requirements apply with regard to patient data processing also. Article 2(1) of the Blood Directive states that the 'blood directive shall apply to the collection and testing of human blood and blood components, whatever their intended purpose, and to their processing, storage, and distribution when intended for distribution.'

6. Traceability

6.1 Data related to Traceability

While the Blood and Tissue directives require that data related to traceability should be kept for a minimum of 30 years, the specific guidance on the data which is required to be retained for traceability reasons, is outlined in the Traceability Directives 2005/61/EC and 2006/86/EC (see appendix 1 to this document)

From the point of view of the right to be forgotten, a BE cannot facilitate this right where there is traceability data that is legally required to be kept. Additionally while not strictly for traceability but rather as required by Article 13, the Blood Directive requires information around the donors health history and eligibility to donate, deferral information and testing carried out to be kept for a minimum of 15 years, which necessarily means that the donor cannot be 'forgotten' for at least a 15 year period once they have provided this information to the BE.

Art 13 of 2002/98 EC states

'*Member states shall take all necessary measures to ensure that blood establishments maintain records of the information required in Annexes II and IV and under Article 29 (b), (c) and (d). The records shall be kept for a minimum of 15 years'*

Where Annex II relates to annual reporting by the BE, Annex IV relates to the basis testing requirements, and Article 29 relates to

(b) information to be provided to donors;
(c) information to be obtained from donors including the identification, health history, and the signature of the donor;

(d) requirements concerning the suitability of blood and plasma donors and the screening of donated blood including

- permanent deferral criteria and possible exemption thereto

- temporary deferral criteria

Practically from the BE's viewpoint this implies that with the exception of for example email addresses/mobile phone numbers, and any associated marketing information, the majority of the donor record is required to be retained for at least 15 years and some of the information continues to be required for a minimum of 30 years. Donor demographic, health history, testing and any deferral information must be kept for a minimum of 15 years under Art 13 and data relating to the collection, processing, storage, release and distribution of blood and blood components must be kept for a minimum of 30 years under Art 14 (1), (3))

In terms of what 15 or 30 years means, it is taken to mean 15 or 30 years from the point when the information was collected/generated by the BE.[4] This would imply that the BE will retain at any given time the last 15 years of the donors health history, the last 15 years' worth of testing records, and deferral information and the last 30 years of donation and associated information.

The following broad categories of data have been identified and agreed as directly relevant to traceability based on the directives:

Category of Data	**Description**
Donor Attendance data	All data pertaining to an individual donation event (for donors who pass screening and who go on to attempt to donate)
Product Data	Data pertaining to the products (components) made from the donation
Hospital Ordering Data	Data relating to hospital orders of blood components.
Issuing Data	Data identifying where and when components were issued to external hospitals and other agencies.
Final Fate Data[5] (where it applies)	Data pertaining to the transfusion of a component into a patient.
Patient Data demographic and health data	Data pertaining to the testing of patient samples on behalf of a hospital either for the provision of blood product or as part of reference services

[4] The standard approach to setting retention periods for records is to retain the record for X period from the date of the record's generation

[5] May not be collected within all EBA member organisations (e.g. where hospital blood bank management is the responsibility of a local hospital and not the Blood Establishment)

As such each of these data sets are legally required to be retained for a min of 15/30 years in line with the directives.

6.2 Additional Categories of Data Retained

While the primary legal basis for the retention of data for BE's is the traceability requirement given by the blood and tissue directives, there are a number of basis within the Data Protection Legislation which also support the processing (to be understood as including retention) as follows (from Recital 45, 46 of GDPR):

- If it is necessary for the performance of a task carried out on the public interest, or
- In the exercise of official authority, or
- Where it is necessary to protect an interest which is essential for the life of the data subject or that of another natural person.

In addition to the traceability data the following broad categories of data are generally being retained by the BE under the requirements of Article 13 on record keeping or for other justifiable reasons. The retention requirement for these records will vary from BE to BE and may be influenced by national legislation or national regulatory guidance.

Category of Data	**Description**	**Basis for retention**
Appointments Management Data	Administrative data relating to booking and management of donor clinic appointments.	Operational reasons
Donor Medical Screening Data	Data pertaining to the responses to donor self-assessment and medical screening.	Required to be retained for a min 15 years under Article 13 of the Blood Directive
Clinical Advice Data	Data relating to clinical advice given to a donor post-donation.	Donor/patient safety reasons
Test Instrument Raw Data	Various data collected by testing instruments in relation to their use – may include donor / donation event identifiers, as well as other supplementary data – e.g. user data, date/time stamps, error logs.	Data integrity reasons
Testing Data	Data pertaining to the microbiology and associated tests performed on donation samples (and their associated results).	Required to be retained for a min 15 years under Article 13 of the Blood Directive
Data Warehouse Data	Wide-ranging data relating to all	Operational/business

	aspects of blood establishment activity, including specific information about individual donors and related donation events etc. *(This data is generally retained in an anonymised form for the purposes of data analysis)*	intelligence reasons The BE would be under an obligation to ensure that the data subject would not be identifiable in any data warehouse or secondary system if a right to be forgotten/ restriction of processing is being upheld The implicated records could be anonymised, allowing the BE to retain the activity but fulfil the data subjects rights.
Audit Trail Data	IT system logs to track usage, user access to records, system errors etc.	Data integrity reasons
Backup Data	Backup data, retained to ensure business continuity / disaster recovery in the event of a major system failure that resulted in loss of data from operational IT system(s). May also be used by some Blood Establishments for traceability, if 30 years of data is not retained in operational IT system(s).	Data integrity reasons
Staff Training and Competency records	Data and records relating to staff training and training history and competency assessments insofar as they are relevant to the collection, storage and processing of blood and blood/tissue components	Operational and staff employment law reasons such as occupational liability

7. Electronic Data

In addition to the paper records generated and retained, Blood Establishments utilise many IT applications and electronic media for the storage of their donor/patient/staff information. There are a number of points for consideration in relation to this.

a) Backups – all critical applications are being backed up on a regular basis to facilitate business continuity and disaster recovery. Most organisations are holding a number of tapes per year permanently to facilitate these aims.
b) Audit trail – most critical applications have a requirement to and generate audit trail of at least all write/modify/delete actions in the database. For information security and integrity purposes these audit trails cannot be modified (with the exception of via elevated privileges) and in practice would not be modified. Where a record is deleted or modified in the application the audit trail will retain a record of the data which has been deleted.

While in principle the right to be forgotten should apply to these scenario's also, in practice it would generally be considered unfeasible in terms of cost and effort and likely to introduce risk around data integrity for example. Once the data has been deleted where possible (or anonymised if necessary) from the application it will be considered to have been 'put beyond use' insofar as access to this data is now highly restricted and not available to the organisation without the specialist help of the IT department. It is considered that this is a practical view which will need to be taken until such times as both backup technologies and audit trail design in the relevant applications are improved/replaced with more suitable tools.

c) Data Warehousing – many Blood Establishments utilise data warehousing applications, i.e. applications which will collate information from various different applications around the organisation, in order to do enterprise reporting.

Enterprise reporting applications like these data warehouses commonly produce reporting on a wide variety of business activities drawing information via either automated or manual means from the primary systems which hold the data. Where a request to exercise the right to be forgotten is agreed to by a BE it would be considered important that the actioning of any such request on a primary system would not replicate to the data warehouse in such a way that the activity itself is lost. For example, if the warehousing application is reporting on the number of new donors in a given year, it would not be considered desirable to lose the record or count of the donor as a new donor. However steps should be taken to anonymise the donor record in the data warehouse in order to meet the donor's request.

d) Raw Data from test instruments – Blood Establishments utilise many automated testing instruments across their testing programmes. These instruments generate significant amounts of raw data which are used to generate a final result that is posted to the donor or patients record. As the technology is replaced these instruments continue to contain legacy raw result data.

For some of the BE's[6] contributing to this paper it is mandatorily required by their regulator that this raw information is traceability data and must be retained to support investigations.

[6] Regulatory direction by the MHRA in the UK

Where no guidance is currently available from the regulator assessment is ongoing into the frequency of any requirement to revisit this data for investigations and the potential risk if it was not available (legacy raw data).

8. Proposed joint approach

8.1 Point where donor cannot be forgotten (start of donor journey)

For simplicity it is useful to consider the donor's engagement and donation journey with the BE as having one or more of the following initial steps:

	Stage	**Process**	**Can Exercise a Right to be Forgotten**
Preclinic	Stage 1	Donor has contacted BE to say they're interested in donating	Yes
	Stage 2	Donor has made an appointment to donate	Yes
	Stage 3	Donor has completed an online or postal health history/health check before coming to the clinic assuming the health check information is not stored in the BE's systems at this point[7]	Yes
At Clinic	Stage 4	Donor has had their demographic information registered	No* from this point on in line with Article 17 of 2002/98/EC it is considered that the donor can no longer exercise a right to be forgotten irrespective of outcome
	Stage 5a	Donor has had health screening completed and are fit to donate today (not deferred)	No
	Stage 5b	Donor has had health screening completed and are not fit to donate today (deferred)	No
	Stage 6	Donor has been put on a bed and had a needle inserted/attempt has been made to insert a needle	No
	Stage 7	Donor has made a successful donation	No

[7] Some online systems in use have the ability to allow the donor enter answers to the health screening questions online and then generate a barcode which can be brought to clinic with those answers encoded, the system retains no record of the health screening questions at that time, it is only when the donor presents to clinic and their barcode is scanned that the health screening becomes part of their record and thus cannot be forgotten

Article 17 of the Blood Directive states '*Member States shall take all necessary measures to ensure that, upon agreement of a* ***willingness*** *to commence the donation of blood or blood components, all donors in the Community provide the information referred to in Article 29(c) to the blood establishment*.'

Article 29(c) further specifies that this information includes '*the identification, health history, and the signature of the donor*'. This information is required to be retained for a minimum of 15 years under Article 13. Our interpretation of this is that once a donor has commenced the session registration process they are ' willing' to donate (as distinct from simply having expressed an interest in donating) and the relevant retention periods becomes applicable, but that prior to this point the donor, should have the right to be forgotten.

In the case of a new donor this would apply to the basic demographic information which may have been registered for them up to this point.

8.2 Point where donor can be forgotten (end of donor interaction with BE)

It is clear that once the information comes under the scope of 'traceability' as defined in the legislation, that it must be kept for a minimum of 15 or 30 years (refer to section 6 and 7). While there is likely to be variability between BE's due to differing local regulations, legal requirements and standards as to whether they apply the strict minimum of 15/30 years the principle for the purposes of the 'right to be forgotten' is that each BE is legally obliged to retain this information for at least these periods. Therefore once a donor has engaged in a session registration on a clinic no request for a right to be forgotten can be considered until at least the minimum traceability periods have elapsed for the different categories of data. After this period has elapsed the BE would need to give careful consideration to facilitating any such request. While the retention periods are expressed as 'minimum' periods and therefore additional retention/restriction of the right to be forgotten could be justified, any such decision should be assessed and carefully documented as for example an indefinite retention period would be hard to justify simply on the basis that the 15/30 year period is a minimum period.

8.3 Tissue

In relation to tissue, e.g. bone marrow, cord blood stem cells, the proposed consensus approach is that a tissue donor should be afforded the 'right to be forgotten' up to the point where they become the donor for a recipient, i.e. until such times as transplant takes place. Unlike the blood donation context a tissue donor will only make a donation in the case where there is an identified recipient. While the tissue donor will have had their relevant medical and other information recorded and an initial sample taken to assess their suitability and to complete HLA typing, there is no traceability requirement and no other legal basis

for retaining the information if requested to 'forget' it, until such times as the donor donates to a recipient.

Although outside the scope of this paper, it is noted that the scenario of living donors who donate for example bone material or deceased donors who donate organs needs to more closely track the blood donation case since the BE or Tissue/Organ establishment is in receipt of the product prior to a recipient being identified. In those cases once the donor has donated, they cannot exercise a right to be forgotten unless and until the product is destroyed unused.

8.4 System Limitations

While the purpose of this document is to find consensus principles and relevant justifications for managing the 'right to be forgotten' in the BE context. It acknowledges that the practical implementation of this policy will necessarily vary from BE to BE because of various IT system limitations, i.e. lack of archiving or delete functionality to allow selective deletion of data, and in some instances due to national legislation. Refer to 9.5 below.

Some points to consider here however include the possibility of anonymising a record in the relevant IT system if it cannot be deleted. In this way the record will be retained and thus the integrity of the IT system also, if it does not support deletion. In the case where a national identity card is being used as the donor's id number for the BE systems, deleting the personal information will only constitute pseudonymisation of the record rather than anonymisation since the connection to the individual will be readily obtainable through other public institutions.

Going forward BE's should also consider their requirements for delete functionality in any IT systems they procure and we would expect to see application developers responding with GDPR compliant functionality of this sort in the coming years.

8.5 Impact of National Legislation

All European BE's are subject to the directives as outlined in Appendix 2. This proposal for a common approach to the application of the right to be forgotten is thus based on the directives. It is acknowledged however that each country also has instantiating national regulations and potentially other associated regulations which may impact on an individual BE's ability to apply the proposed approach. The group however considers it beneficial to apply a consistent approach where possible and where it is not possible this document will at least function as a consensus baseline/foundation on which the national legislation can then sit.

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Appendix 1– Blood and Tissue Directives traceability and retention references

Blood		
Directive 2002/98/EC	Art 13 – Record Keeping 1. Member States shall take all necessary measures to ensure that blood establishments maintain records of the information required in Annexes II and IV and under Article 29(b), (c) and (d). The records shall be kept for a minimum of 15 years. Annex II Reporting Annex IV Basic Test Requirements Art 29 (b) information to be provided to donors (c) information to be obtained from donors – including identification, health history and signature (d) requirements concerning the suitability of blood and plasma donors and the screening of donated blood including — permanent deferral criteria and possible exemption thereto — temporary deferral criteria; Art 14 – shall take all necessary measures in order to ensure that blood and blood components collected, tested, processed, stored, releases and/or distributed on their territory can be traced from donor to recipient and vice versa.	15 years • Reporting to HPRA • Testing • Information to be provided to donors • Information to be obtained from donors including identification, health history, signature • Permanent and temporary deferral criteria and information relating to the suitability of the blood/plasma donor to donate

Directive 2005/61/EC	Art 4 Record of data on traceability Member States shall ensure that blood establishments, hospital blood banks, or facilities retain the data set out in Annex I for at least 30 years in an appropriate and readable storage medium in order to ensure traceability.	30 years Appendix 1 BY BLOOD ESTABLISHMENTS 1. Blood establishment identification 2. Blood donor identification 3. Blood unit identification 4. Individual blood component identification 5. Date of collection (year/month/day) 6. Facilities to which blood units or blood components are distributed, or subsequent disposition. BY FACILITIES 1. Blood component supplier identification 2. Issued blood component identification 3. Transfused recipient identification 4. For blood units not transfused, confirmation of subsequent disposition 5. Date of transfusion or disposition (year/month/day) 6. Lot number of the component, if relevant.
Tissue		
Directive 2004/23/EC	Art 8 – Traceability 4. Tissue establishments shall keep the data necessary to ensure traceability at all stages. Data required for full traceability shall be kept for a minimum of 30 years after clinical use. Data storage may also be in electronic form.	No specific information outlined

Directive 2006/86/EC	Art 9 – Traceability 1. Tissue establishments shall have effective and accurate systems to uniquely identify and label cells/tissues received and distributed. 2. Tissue establishments and organisations responsible for human application shall retain the data set out in Annex VI for at least 30 years, in an appropriate and readable storage medium.	30 years Annex IV A. BY TISSUE ESTABLISHMENTS 1.Donor identification 2.Donation identification that will include at least: — Identification of the procurement organisation or Tissue establishment — Unique Donation ID number — Date of procurement — Place of procurement — Type of donation (e.g. single v multi-tissue; autologous v allogenic; living v deceased) 3. Product identification that will include at least: — Identification of the tissue establishment — Type of tissue and cell/product (basic nomenclature) — Pool number (if applicable) — Split number (if applicable) — Expiry date — Tissue/cell status (i.e. quarantined, suitable for use etc.) — Description and origin of the products, processing steps applied, materials and additives coming into contact with tissues and cells and having an effect on their quality and/or safety. — Identification of the facility issuing the final label 4. Human application identification that will include at least: — Date of distribution/disposal — Identification of the clinician or end user/facility

Appendix 2 – National Legislation

United Kingdom	• The Blood Safety and Quality Regulations 2005
Ireland	• SI 360/05: European Communities (Quality and Safety of Human Blood and Blood Components) Regulations 2005 • SI 562/2006: European Communities (Quality System for Blood Establishments) Regulations 2006 • SI 158/06: European Communities (Quality and Safety of Human Tissues and Cells) Regulations 2006 • SI 598/07: European Communities (Human Tissues and Cells Traceability Requirements, Notification of Serious Adverse Reactions and Events and Certain Technical Requirements) Regulations 2007
Denmark	• Danish Transfusion Medicine Standards (TMS: https://dski.dk/gaeldende-version/
Malta	• CHAPTER (CAP) 483 HUMAN BLOOD AND TRANSPLANTS ACT
Belgium	• Belgian Royal Decree April 4th 1996