The Right to be Forgotten under the General Data Protection Regulation (GDPR)

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Background

- EBA DPO/Privacy working group set up early 2018
- Discussion re challenges of implementing the new GDPR regulation in the blood establishment context
- Right to 'erasure' and right to be forgotten considered to be one point that could benefit from discussion between the different BE's to see if a standard interpretation could be provided
- Would support standardised responses being provided to data subjects

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Legal Framework – GDPR Right to be forgotten

- Under the new GDPR legislation, individuals have a number of rights in relation to the way organisations process their personal data, including 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:*
  - ✓ *The personal data is no longer necessary in relation to the purposes for which they were collected or otherwise processed;*
  - ✓ *the data subject withdraws consent on which the processing is based and there is no other legal ground for processing*
  - ✓ *the data subject objects to the processing and there are no overriding legitimate grounds for the processing*
  - ✓ *the personal data have been unlawfully processed;*
  - ✓ *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;*
  - ✓ *the personal data have been collected in relation to the offer of information society services referred to in Article 8(1).*

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Legal Framework – GDPR Right to be forgotten Exemptions

- 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.*

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Legal Framework – Blood and Tissue Directives

Directive	Text	Retention Period
Blood Directive Directive 2002/98/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))	15 years - • Annual reports • Testing • Information to be provided to donor • Information to be obtained from donors including ID, health history, signature • Permanent and temporary deferral criteria • Information relating to the donors eligibility
Implementing the Blood Directive - Traceability Requirements and Notification of SAE/SAR's 2005/61/EC	'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)	30 years - Annex 1 - data includes • Establishment ID • Donor id, • Date of collection • Component id • Distribution information • Final fate

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Legal Framework – Blood and Tissue Directives

Directive	Text	Retention
Tissue directive Directive 2004/23/EC	'data required for full traceability shall be kept for a minimum of 30 years after clinical use.' (Article 8(4))	No specific information outlined
Implementing the Tissue Directive -Traceability Requirements and Notification of SAE/SAR's 2006/86/EC:	' 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.' (Article 9(2))	30 years , includes - • Donation id • Donor id • Date /place of procurement • Product id • Type of donation • Product identification • Expiry • Date of distribution • Identification of clincian or end user/facility

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Where does Retention Begin?

- Variation among the group as to at what point once a donor begins to share information with us, they can no longer be forgotten.
- Range of positions from once the donor or potential donor makes contact to once the donor has attempted a donation
- Art 13 of 2002/98/EC on record keeping addresses this point

'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 basic 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

- Scenario for Tissue is clearer

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Donor Journey - Start

	Stage	Process	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*	Yes
At Clinic	Stage 4	Donor has had their demographic information registered	No – Art 13
	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

Donor can no longer be forgotten after this point

Donor Journey - Start

- *'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.'* (Art 17 2002/98/EC)
  - ✓ Once a donor has commenced the session registration process they are ' willing' to donate
  - ✓ Distinct from simply having expressed an interest in donating
  - ✓ The relevant retention period then becomes applicable
  - ✓ Prior to this point the donor, should have the right to be forgotten.

- Beginning of retention requirement for Tissue is clearer
  - ✓ should be afforded the 'right to be forgotten' up to the point where they become the donor for a recipient
  - ✓ will only make a donation where there is an identified recipient.
  - ✓ relevant medical information and sample already taken to assess their suitability
  - ✓ however 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.

Donor Journey - End

- It is accepted that the directives limit BE's ability to allow the right to be forgotten
- Annex I of 2005/61/EC as to what constitutes traceability data is minimal – donor id, date of collection, blood component, issued to, distribution, final fate
- Different BE's are interpreting them in different ways, for various reasons including practicality, system limitations etc.
  - ✓ min 30 years – but actually keeping everything for ever
  - ✓ 30 years for Health history (even though it's only needed for 15) for practicality
  - ✓ Test data for 30 rather than 15 because of national regulator etc..
- What does 15 or 30 years retention mean?
  - ✓ it is taken to mean 15 or 30 years from the point when the information was collected/generated by the BE.
  - ✓ 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.

Donor Journey - End

- Categories of data to be retained for a minimum of 15 /30 years under the directives
  - ✓ Donor medical screening
  - ✓ Donor Attendance data
  - ✓ Testing data
  - ✓ Product data
  - ✓ Hospital Ordering and Issuing data
  - ✓ Final Fate Data
  - ✓ Patient demographic and health data
- Records being retained for other reasons, donor/patient safety, operational, data integrity, legal/employment
  - ✓ Appointments Management data
  - ✓ Clinicial Advice data
  - ✓ Test instrument Raw data
  - ✓ Data Warehouse data
  - ✓ Audit Trail and Backup data
  - ✓ Staff training records

Final Comments

- Understand there is local national legislation in many countries that may further restrict the right to be forgotten
- Useful to have a base position
- EU work programme for 2021 include revision of the Blood and Tissue directives
- Additional points for discussion and consideration:
  - ✓ use of national identity numbers
  - ✓ how to practically manage facilitating the right to be forgotten
  - ✓ system limitations
  - ✓ anonymisation and pseudonymisation
  - ✓ Relationship to retention and destruction policies
  - ✓ Research