

Information on the processing of personal data in the database referred to in Article 35, § 2 and Article 64, § 2 of the Act of 6 July 2007 on medically assisted reproduction and the destination of supernumerary embryos and gametes.

To enable fertility centres to verify that gametes or embryos from the same donor or from the same donor pair cannot result in the birth of children in more than six different women (two desire parents of the female sex, who declare a joint desire to have children, are considered one woman), a system has been set up for the exchange of the required information between fertility centres. The application automatically calculates this quota based on the information provided and the recorded inseminations, distribution and implantations. The system is managed by the Federal Agency for Medicines and Health Products (FAMHP), which collects and centralises personal data from fertility centres in a database called Fertidata.

Your privacy is of paramount importance to the FAMHP. This FAMHP document gives you information about the protection of your personal data processed by the FAMHP, about your rights and how to exercise those rights.

All personal data (that is, any data relating to an identified or identifiable natural person) that you entrust to the FAMHP will be treated with due care. This of course means that all processing of these personal data will be carried out in accordance with Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (GDPR).

In accordance with the provisions of the General Data Protection Regulation (GDPR), you are entitled to receive clear information about the processing of your personal data.

The FAMHP can only answer questions relating to the data processed in the 'Fertidata' application.

For all other questions, such as those relating to your medical records, please contact the fertility centre you are in contact with.

1. Why and on what basis does the FAMHP process your personal data?

- A. The legislation that governs the processing of these data consists of:
- the Act of 6 July 2007 on medically assisted reproduction and the destination of supernumerary embryos and gametes (hereinafter referred to as 'the Act');
- the Royal Decree of 17 December 2023 on the system of exchange of information between fertility centres referred to in Articles 35, §2 and 64, §2 of the Law of 6 July 2007 on medically assisted reproduction and the destination of supernumerary embryos and gametes (hereinafter referred to as the 'Royal Decree').
- B. The purposes for which processing is carried out are as follows.

In order to enable healthcare professionals authorised by the fertility centres to carry out the necessary checks to ensure compliance with Article 26 of the Act, a system for exchanging the data required for this purpose between the fertility centres is being established. The management of that system will be entrusted to the FAMHP, which will collect the data defined in point 2 from the fertility centres and centralise them in a database.

The FAMHP inspectors will have access to the database to carry out their tasks referred to in Article 72/1, § 2 of the Law.

As part of the data exchange system referred to in paragraph one, personal data will be processed by recording them in the database under the responsibility of healthcare professionals authorised by the fertility centres.



2. What personal data will be processed by the fertility centres? Categories of personal data processed:

A. Donors of gametes, or in the case of supernumerary embryos, the donors of gametes used to create the embryos:

- National register number or, if not available:
 - the number referred to in Article 8, § 1, 2° of the Act of 15 January 1990 concerning the creation and organisation of a Crossroads Bank of Social Security; or, if not available:
 - the number or pseudonym assigned to the donor by the foreign institution that supplied the gametes to the Belgian fertility centre, and the code of the European tissue establishment referred to in Article 2, 40°, of the Act of 19
 December 2008 on the procurement and use of human tissue material intended for medical applications in humans or for scientific research; or, if not available:
 - a code consisting of the following elements, in the order indicated:
 - 1. the first two letters of the person's first name;
 - 2. the first two letters of the person's surname;
 - 3. the person's date of birth;
 - 4. the person's nationality.
- The number of women who have had children with embryos from the same donor or donor pair.

B. Women receiving the embryos:

- National register number or, if not available:
 - the number referred to in Article 8, § 1, 2° of the Act of 15 January 1990 concerning the creation and organisation of a Crossroads Bank of Social Security; or, if not available:
 - a code consisting of the following elements, in the order indicated:
 - 1. the first two letters of the person's first name;
 - 2. the first two letters of the person's surname;
 - 3. the person's date of birth;
 - 4. the person's nationality.
- Information about a joint desire to have children with a female partner, if applicable.
- Pregnancy resulting from the implantation of donated embryos.
- Birth of a living child (or children), a viable child (or children) after implantation.

C. If applicable, information about a joint desire to have children with a female partner:

- National register number or, if not available:
 - the number referred to in Article 8, § 1, 2° of the Act of 15 January 1990 concerning the creation and organisation of a Crossroads Bank of Social Security; or, if not available:
 - the number or pseudonym assigned to the person concerned by the foreign institution that supplied the gametes to the Belgian fertility centre, and the code of the European tissue establishment referred to in Article 2, 40°, of the Act of 19 December 2008 on the procurement and use of human tissue material intended for medical applications in humans or for scientific research; or, if not available:
 - a code consisting of the following elements, in the order indicated:
 - 1. the first two letters of the person's first name
 - 2. the first two letters of the person's surname
 - 3. the person's date of birth
 - 4. the person's nationality.

All personal data will be stored in the database in pseudonymised form only. The depseudonymisation of this data is prohibited.



Cookies

The FAMHP uses small files (cookies) which are placed on the hard disk of the computer belonging to users of this website, in order to remember your choice of language and thereby making our website easier to use.

3. How long will your personal data be stored?

- The data will be stored for 50 years, counting from the date of the data most recently entered.
- o The data will be deleted once the donor of male gametes reaches 70 years of age.

4. With whom do we share your personal data?

The data used to calculate the quota are provided by the fertility centres. These data are shared with technical subcontractors of Smals and with the eHealth platform.

5. What are your rights and how can you exercise them?

You have the following rights.

- Access: you can obtain information about the processing of your personal data, as well as a copy of the data concerned.
- Rectification: if you believe that your personal data are incorrect or incomplete, you may ask that the personal data concerned be corrected.
- Limitation: you can request that the processing of your personal data be limited to the cases referred to in Article 18 of the GDPR.

You cannot ask for your personal data to be deleted.

You cannot exercise your right to portability and you cannot object to the processing.

If you wish to exercise any of these rights, or if you have any questions about the FAMHP's processing of your personal data, please contact the FAMHP's Data Protection Officer at dpo@faqq.be or at the following address:

Federal Agency for Medicines and Health Products – FAMHP For the attention of the Data Protection Officer

Federal Agency for Medicines and Health Products Avenue Galilée 5/03 B-1210 BRUSSELS

You must include a scan/copy of your identity card so that the FAMHP can identify you.

Your request will be processed within 30 calendar days. In exceptional cases, this period may be extended by 60 days.

If you believe that the FAMHP has not processed your personal data in accordance with applicable law, you have the right to lodge a complaint with the Data Protection Authority.

Data Protection Authority

Rue de la Presse 35 B-1000 BRUSSELS contact@apd-gba.be