

**Notification of a suspected serious adverse reaction in donors of tissue,
tissue preparations, or stem cells pursuant to Section 63i AMG (German Medicinal Products Act)**

Form
G1b

to the Paul-Ehrlich-Institut, Unit Pharmacovigilance II, Paul-Ehrlich-Straße 51-59, 63225 Langen, Germany



Please see: www.pei.de/gewebevigilanz for further information

Email: pharmakovigilanz2@pei.de
Phone: +49 06103 77-3117

Please do not fill out this field

PEI No.:

Fax.: +49 06103 77-1268

Reporting tissue establishment:

Street, number:

Postal code /zip code:

City or town:

Phone:

Fax:

Internal case number

Donor data

Initials: _____ Date of birth: _____ female male

Tissue or tissue preparation

Type of tissue/tissue preparation

Oocytes (autologous) Haematopoietic stem cells (bone marrow) Autologous donation Allogeneic donation

Other: _____

Single European Code/SEC (40 characters) or ID code

Date of collection

Date of transplantation

Tissue establishment Name: _____ **EU tissue establishment code:** _____

Medication related to donation (e.g. stimulation protocol as part of assisted reproduction):

Type of application of the tissue/tissue preparation: _____

Information on serious adverse reaction of the donor

Local reaction

Systemic reaction

Ovarian hyperstimulation syndrome (OHSS) Severity (Grade): III IV V (according to Golan) OR

Severity (Grade): III (according to WHO)

Other reaction: _____

Hospitalisation: No Yes Duration: _____

Outcome of the reaction:

Recovered

Recovered with sequelae

Death

Onset of the reaction: _____ **Duration of the adverse reaction:** _____

Causality assessment: Confirmed Probably Possible Unlikely Excluded

Final report will follow

Action(s) taken:

Other notified organisations (e.g. BfArM (Federal Institute for Drugs and Medical Devices)): _____

Impact on quality and safety of the tissue /tissue preparation procured:

No

Yes Specify: _____

Information on the person reporting the reaction:

Last Name:

First name:

Phone No.:

Postal code /zip code:

City/town:

Fax No.:

Email:

Signature:

Date: