

**Notification of a serious adverse reaction in the recipient in connection with the transplantation of tissues, tissue preparations or stem cells pursuant to Section 63i AMG (German Medicinal Products Act)**



Form  
G1a

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

Please see: [www.pei.de/gewebevigilanz](http://www.pei.de/gewebevigilanz) for further information

Email: [pharmakovigilanz2@pei.de](mailto: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:

Postal code/zip code:

City or town:

Phone:

Fax:

**Internal case number**

**Information on the recipient**

Initials: \_\_\_\_\_ Date of birth: \_\_\_\_\_  female  male

Underlying disease: \_\_\_\_\_

Indication of transplantation: \_\_\_\_\_

**Tissue or tissue preparation**

Type of tissue/tissue prep.    Single European Code/SEC (40 characters) or ID code    Date of procurement    Date of transplantation

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**Tissue establishment**

Name: \_\_\_\_\_ EU tissue establishment code: \_\_\_\_\_

**Legal basis (for activities of the tissue facility with regard to the tissue/tissue preparation affected):**

Authorisation pursuant to Sections 20b and c AMG     Authorisation pursuant to Section 21a (1) AMG     Authorisation pursuant to Section 25 (1) AMG

**Type of donation**     Post-mortem donation     Living donation     Autologous donation

**Type of use:** \_\_\_\_\_

**Information on the serious adverse reaction**

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**Suspected diagnosis:**

Infection / Transmissible diseases     Neoplasia     Allergic reaction  
 Incompatibility / rejection     Functional defect of the tissue/tissue preparation  
 Other reaction: \_\_\_\_\_

**Onset of reaction:** \_\_\_\_\_    **End of reaction:** \_\_\_\_\_

**Outcome of reaction:**  Recovered     Recovered with sequelae  
 Death    Cause of death: \_\_\_\_\_     Autopsy performed     No autopsy performed

**Course and treatment (e.g. re-transplantation):**

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(attach informal report or medical report, if required)

**Assessment of relationship with the tissue/tissue preparation:**

Confirmed     Likely     Possible     Unlikely     Excluded     Final report will follow

**Information on the person reporting the reaction:**

**Last name:** \_\_\_\_\_    **First name:** \_\_\_\_\_    **Phone No:** \_\_\_\_\_  
**Postal code/zip code:** \_\_\_\_\_    **City or town:** \_\_\_\_\_    **Fax No:** \_\_\_\_\_  
**Date of reporting:** \_\_\_\_\_    **Email:** \_\_\_\_\_  
**Signature:** \_\_\_\_\_    **Date:** \_\_\_\_\_