

WHAT IS BIOVIGILANCE ?

Surveillance of incidents occurring from the procurement to the administration and surveillance of adverse events to the living donor or to the patient linked or possibly linked to the use of human organs, tissues, cells and ancillary products.
The aim of biovigilance is to improve the safety of human organs, tissues, cells and ancillary products.

The concept of vigilance on biological products dates back to the French bioethics law dated July, 29 1994. The biovigilance network has been set up by the decree n°2003-1206 published on December, 19, 2003.

APPLICATION FIELDS

Products included in the biovigilance field	Products excluded from the biovigilance field
<ul style="list-style-type: none"> - Human organs, tissues or cells used for therapeutic purpose as well as ancillary products - Cell therapy preparations - Medical devices including products of human origin - Ancillary products 	<ul style="list-style-type: none"> - Gamets (Biomedecine Agency) - Labile blood products - Cell and gene therapy products relevant to a marketing authorization - Any other medical device - Medicinal products from human origin (Blood derived medicinal products...) - In vitro diagnosis devices

► Scope of activities



WHAT TO DECLARE ?

- **Adverse Event**
Unexpected and untoward clinical manifestation that happens to the living donor or to the recipient.
Examples : allergic reaction, keratitis
- **Serious adverse event**
 - death,
 - life threatening of the patient, the living donor or to the recipient,
 - safety issue for one or several living donors and/or one or several recipients.*Examples* : infectious diseases, anaphylactic reaction, neurological troubles
- **Incident**
Failure from an element at one step of the process (procurement, testing, processing, storage...) that can entail an adverse event for the patient, the living donor or for the recipient.
Examples : microbiological contamination, incomplete serological data
- **Serious incident**
 - repetition,
 - safety issue for one or several living donors and/or one or several recipients,
 - induce serious adverse events.*Examples* : viral inactivation process failure

THE BIOVIGILANCE NETWORK

There is **no regional level** in the biovigilance network.

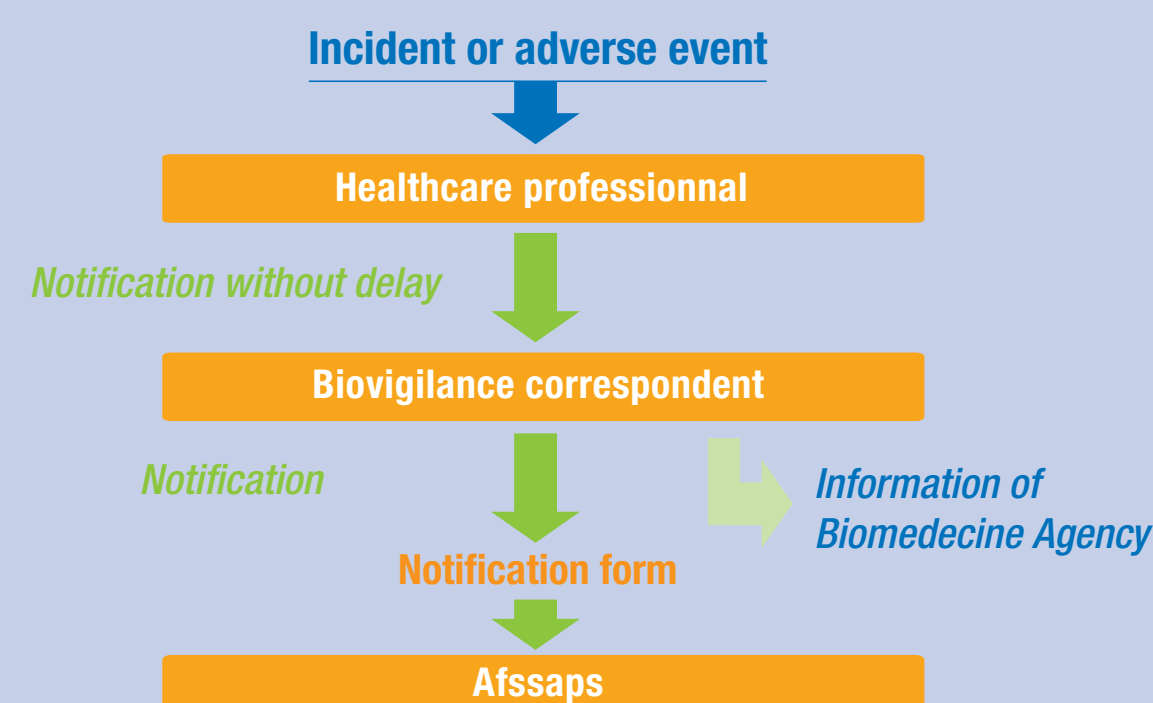
Local level :

- **all healthcare professional**
Each healthcare professional should notify to the biovigilance correspondent, without delay, any incident or adverse event which may be attributed to the health products or to the activities concerned by biovigilance.
- **biovigilance correspondent "on site"**
One biovigilance correspondent must be designed in each tissue or cell establishment and in each health establishment that collects or grafts human organs, tissues or cells.

National level :

- **Biomedecine Agency**
Ensures graft distribution (organs and tissues).
 - **Afssaps**
Responsible for the organisation of the biovigilance network at a national level : coordination of biovigilance local network, evaluation of biovigilance notifications, coordination of national measures (alerts, information, recommendations...).
- Afssaps also ensures that procedures are implemented in tissue / cell establishments as well as in health establishments.

NOTIFICATION PROCEDURE



NOTIFICATION FORM

SOME DATA (2004 - 2006)

108 incidents or adverse events notified in 2004	155 incidents or adverse events notified in 2005	94 incidents or adverse events notified between 1 st January and 30 September 2006
<ul style="list-style-type: none"> ► 68 incidents (3 organs, 7 tissues, 40 cells, 18 ancillary products) ► 40 adverse events (14 organs, 5 tissues, 15 cells, 6 ancillary products) 	<ul style="list-style-type: none"> ► 100 incidents (45 organs, 19 tissues, 9 cells, 24 ancillary products) ► 55 adverse events (25 organs, 4 tissues, 24 cells, 3 ancillary products) 	<ul style="list-style-type: none"> ► 67 incidents (24 organs, 21 tissues, 15 cells, 7 ancillary products) ► 27 adverse events (12 organs, 4 tissues, 11 cells)