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The reproductive system account for 85 % of notifications of serious adverse events and serious adverse reactions related to tissues and cells

The annual biovigilance report includes all serious adverse events and reactions occurring during the treatment and use of substances of human origin from 1 January 2023 to 30 June 2024. In 2023, the reproductive system accounted for the majority of notifications.

Every year, users of substances of human origin (SoHO), Belgian tissue establishments and hospitals must report all serious adverse events and reactions (SAEs and SARs) that have occurred when processing and using tissues and cells, to the FAMHP Biovigilance Entity.
The annual report 2023 includes all those occurring between 1 January 2023 and 30 June 2024.

Biovigilance ensures systematic monitoring, from donor selection to recipient follow-up, in order to guarantee safer and more efficient use of tissues and cells.

Key points in 2023

- 281 notifications, a relatively stable number since 2020.
- 83 % of notifications come from tissue establishments, 17% from hospitals.
- 85 % of notifications relate to the reproductive system, followed by stem cells, the musculoskeletal system and the cardiovascular system.
- 7 cases of SAR related to the reproductive system recorded.
- 22 cases of SAR reported amongst SoHO donors of the reproductive system.
- 75 cases of SAE for the reproductive system compared with 13 for the non-reproductive system (bones, tendons, heart valves, cornea, etc).

Read the full report.

Origin of the data
The data from 45 Belgian establishments, 26 of which specialised in reproductive types of SoHO and 19 in other types of SoHO, was sent to the FAMHP Biovigilance Entity.
Improving the quality of reports of serious adverse reactions and events enhances the safety and efficacy of the use of substances of human origin.
These statements benefit all parties concerned: patients, healthcare professionals, tissue establishments and the healthcare system.

Read the full report

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