

Eventi avversi nelle Banche degli Occhi: uno sguardo sull'Italia e l'Europa

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art 3

"evento avverso grave": qualunque evento negativo collegato con l'approvvigionamento, il controllo, la lavorazione, lo stoccaggio e la distribuzione di tessuti e cellule, che possa provocare la trasmissione di malattie trasmissibili, la morte o condizioni di pericolo di vita, di invalidità o incapacità dei pazienti, o ne produca o prolunghi l'ospedalizzazione o lo stato di malattia

"reazione avversa grave": una risposta non voluta nel donatore o nel ricevente, compresa una malattia trasmissibile, connessa con l'approvvigionamento o l'applicazione sull'uomo di tessuti o cellule, che provochi la morte, metta in pericolo la vita o produca invalidità o incapacità dell'interessato, o ne produca o prolunghi l'ospedalizzazione o lo stato di malattia



Guidance for Competent Authorities

Deviations from Standard Operating Procedures in TEs, or other adverse events, which have implications for the quality and safety of tissues and cells should result in SAE reporting to the CA, even if the event occurred only in one TE, when one or more of the following criteria applies:

- inappropriate tissues/cells have been distributed for clinical use, even if not used

- the event could have implications for other patients or donors because of shared practices, services, supplies or donors

- the event resulted in a mix-up of tissues or cells

- the event resulted in loss of any irreplaceable autologous tissues or cells or any highly matched allogeneic tissues or cells

- the event resulted in the loss of a significant quantity of unmatched allogeneic tissues or cells.*



The NOTIFY Guide On Vigilance and Surveillance

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**Vigilance and Surveillance (V&S) of Medical Products
of Human Origin (MPHO)**

Medical Products of Human Origin type - MPH0

(Expand all) (Clear)

Organs

Blood

Cells

Tissues

Adipose tissue

Amniotic Membrane

Cardiovascular

Dura mater

Musculoskeletal

Nerve

Ocular

Cornea

Sclera

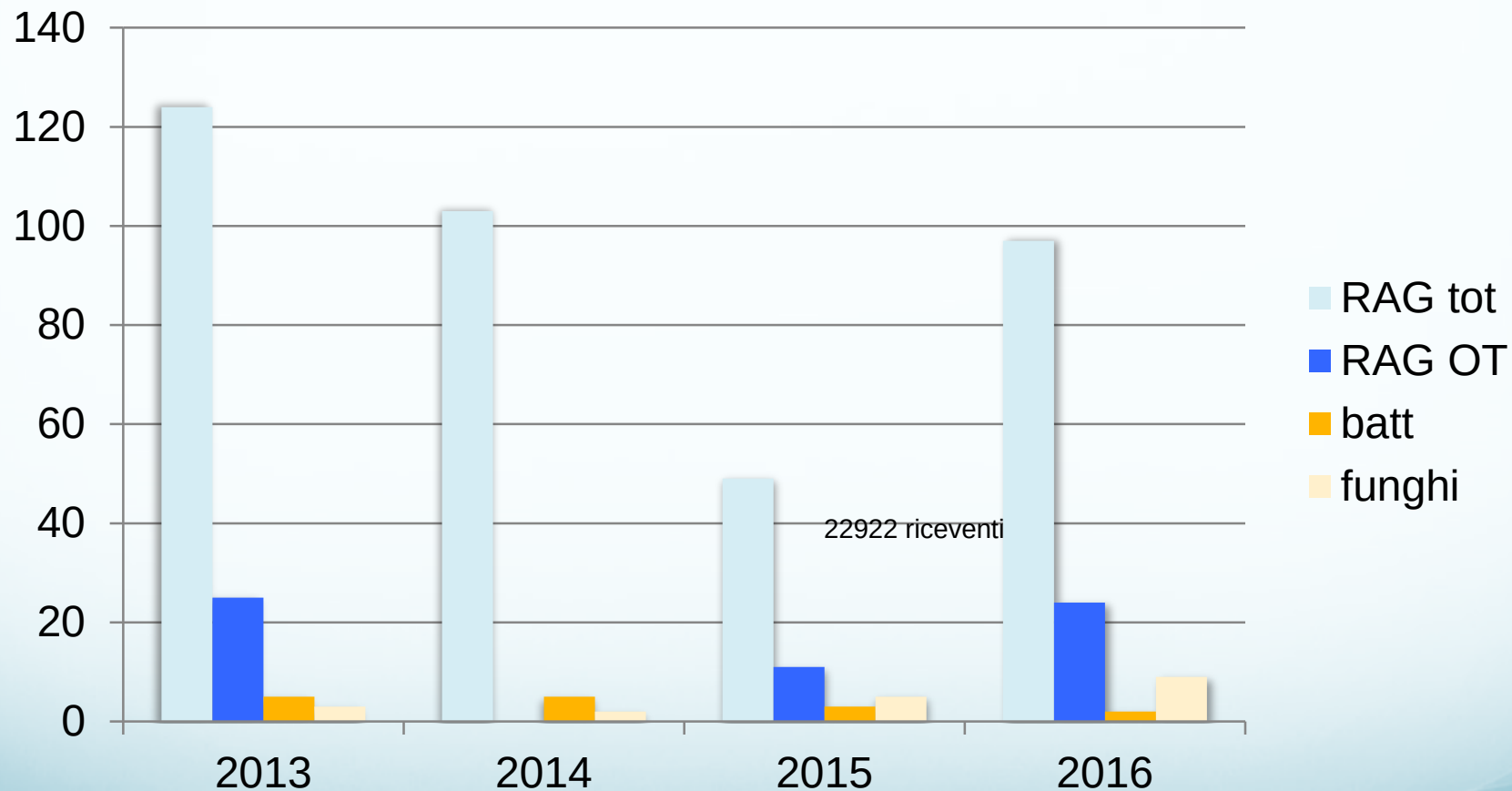
Skin

Reproductive

MPH0-Derived medicinal products

Record ID	Adverse occurrence	References
	Estimated frequency: Corneal specimens with Fuchs' dystrophy displayed numerous round highly reflecting guttae at the level of the corneal endothelium. Donor corneas Demonstration of Imputability or Root cause: Presence of guttae identified by means of light microscopy at the end of organ culture. Note: Specular microscopy is used for Imputability grade: 3 Definite/Certain/Proven Expert comments for publication:	
1120	Adverse occurrence description: Cornea lamel released with contamination of Candida lipolytica Adverse occurrence type: Risk of harm => Unsuitable MPHO released for clinical use - no harm MPHO type: Tissues => Ocular => Cornea Time to detection: N/A Alerting signals, symptoms, evidence of occurrence: Microbiology of cornea lamel positive for C. lipolytica just after the cornea lamel was released and transported to Estimated frequency: N/A Demonstration of Imputability or Root cause: Transplant postponed Imputability grade: Expert comments for publication:	1 reference
1110	Adverse occurrence description: Persistent central haze after cornea transplantation Adverse occurrence type: Harm to a Recipient => Miscellaneous complications => Graft failure MPHO type: Tissues => Ocular => Cornea Time to detection: N/A Alerting signals, symptoms, evidence of occurrence: Best corrected visual unknown Estimated frequency: Two similar reports in 2012 and five in 2011 Demonstration of Imputability or Root cause: Extensive investigation of all SAR didn't lead to a cause. Some recipient had a second transplantation Imputability grade: Expert comments for publication:	1 reference

Eventi e reazioni avverse gravi report annuali CE



Eventi e reazioni avverse gravi in Italia

	2014	2015	2016	2017	2018
Tot EAG	16	15	15	12	16
EAG TO	6	10	4	3	6
varie	5	9	4	0	3
positività	1*	1*	0	3*	3
TOT RAG	2	5	3	4	8
RAG TO	1	1	1	4	6
varie	0	0	1	1	0
infezioni	1pseudomonas	1 batt	0	1endoft 1 inf lenticolo	3 inf in pretagliata 2 endoft 1uveite



NOTIFYLIBRARY

The Global Vigilance and Surveillance Database for Transplantation and Assisted Reproduction

