Federal agency for medicines and health products

TISSUE BANKING AND BIOVIGILANCE IN BELGIUM

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famhp

.be

Legal basis

- Law of 13 06 1986: organ transplantation
- Law of 06 07 2007: ART
- Law of 19 12 2008: procurement and use of human body material for medical application on humans or for scientific research.
- Royal decree of 28 09 2009: quality and safety rules for the activities regarding HBM.
- Royal decree of 28 09 2009: general conditions for the authorisation of TE.
- Royal decree of 28 09 2009: rules concerning notification of serious adverse reactions and serious adverse events regarding the HBM.
- Royal decree of 28 09 2009: modification of RD of 23 10 1964 regarding the standards for hospitals and their departments.

Tissue establishments

Bank for human body material (HBM) : organised structure that can undertake all activities of procurement, testing, preparation, preservation, storage, distribution and export (import will require a separate authorisation). The bank for HBM must be operated by an authorised not for profit hospital.

Intermediary structure: organised structure that can prepare, preserve, store and distribute HBM, in collaboration with a bank for HBM. An intermediary structure may have a profit objective.

Production establishment: organised structure that can undertake all activities, but only in view of the industrial production of ATMP (somatic cell therapy, gen therapy, or tissue manipulation), and this in view of a therapeutic and predetermined use that is purely autologous. A production establishment may also have a profit objective.

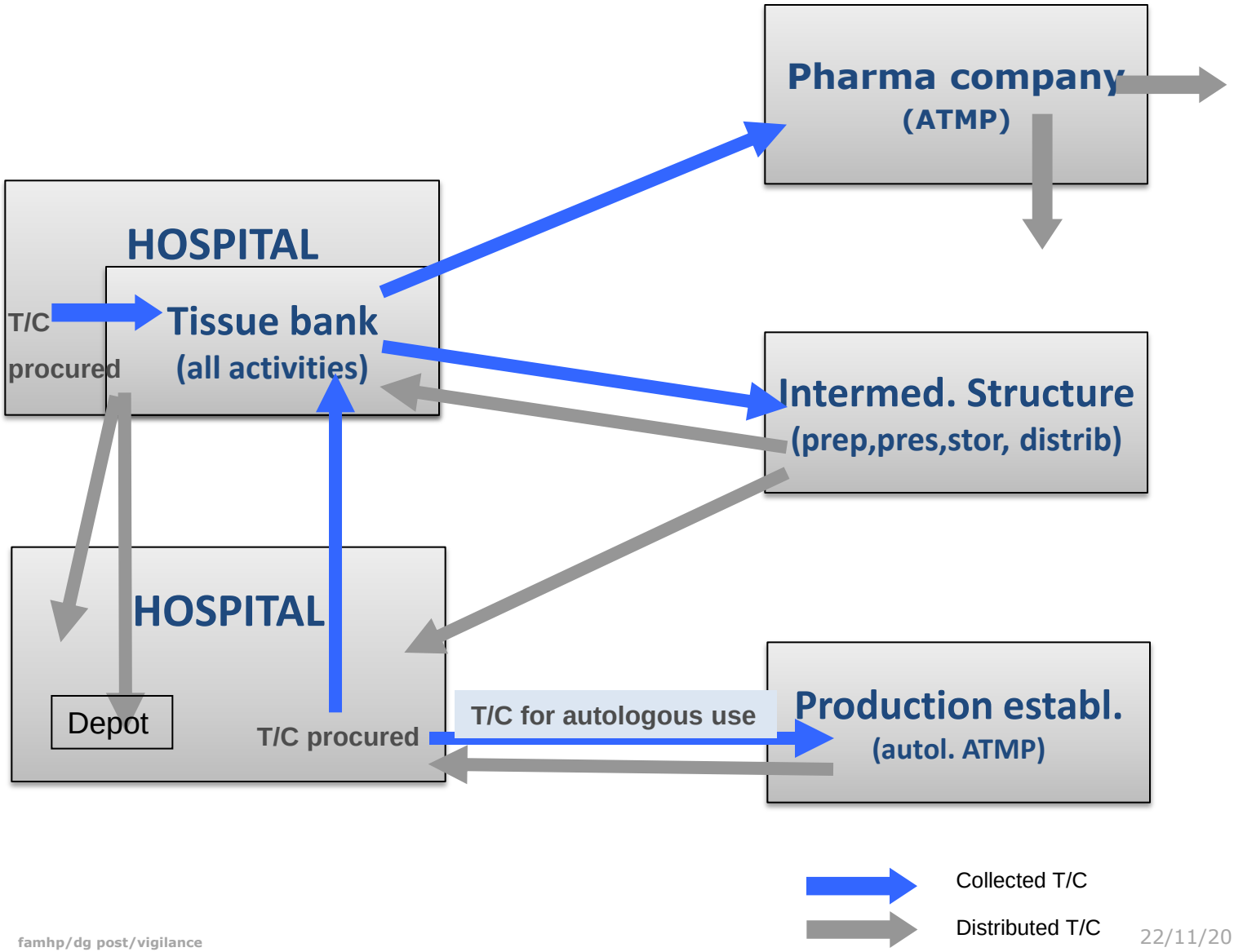
Tissue bank for HBM

Some specificities

1. Procurement HBM for human application:
   - Responsibility: MD
   - In a hospital (exceptions: peripheral HPC: also in blood establishment; male gametes)
   - Insurance: no fault compensation due to damage following procurement./collection T/C;
   - Procurement and storage for autologous or allogeneic deferred use not allowed, exception: for patient suffering from a pathology or with scientific proven risk for pathology for which HBM treatment is scientifically proven, and HBM remains available for therapeutic use in other patients (registered).

2, Use of HBM:
   - In hospital.

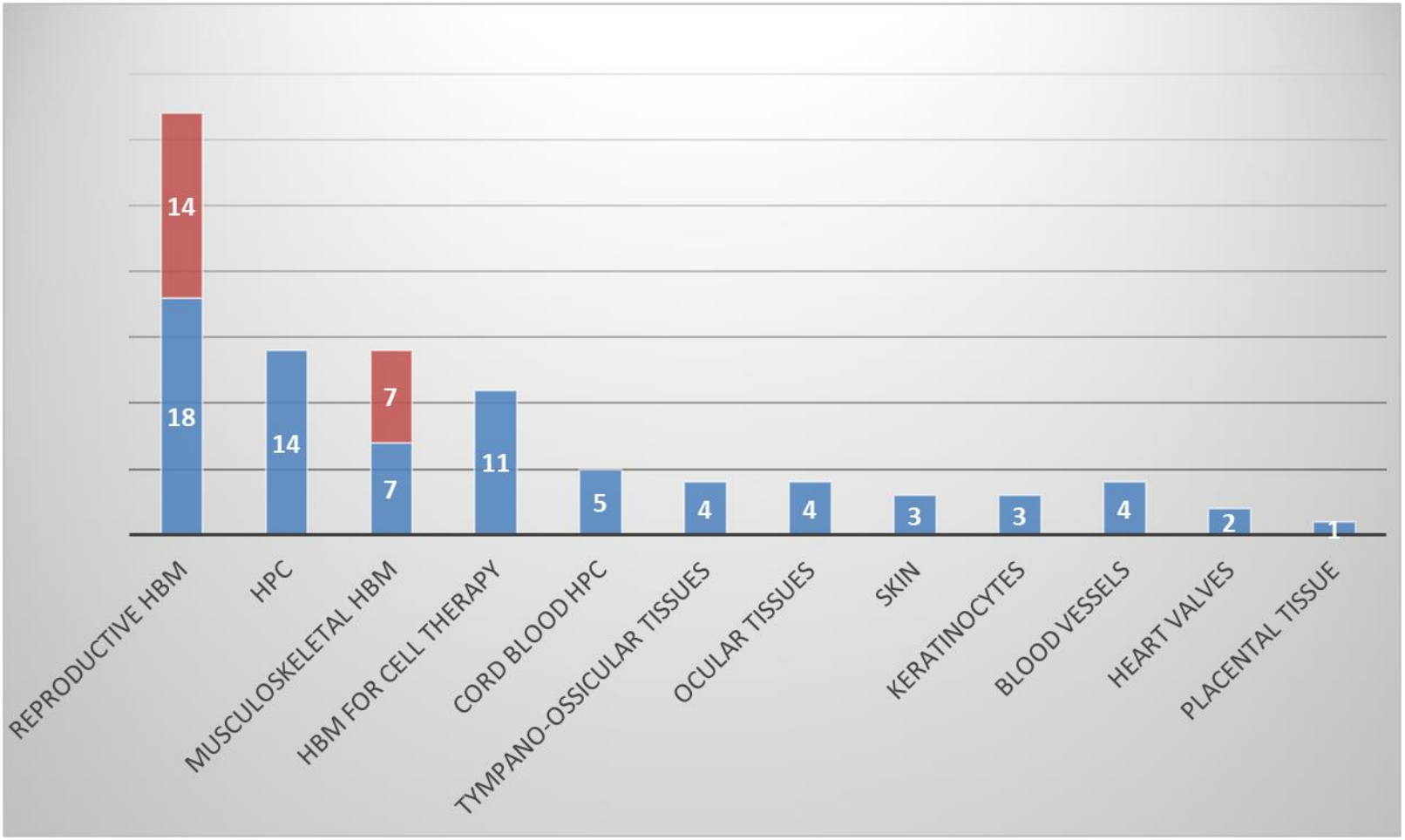
Flow of tissues and cells



Number of authorised tissue establishments

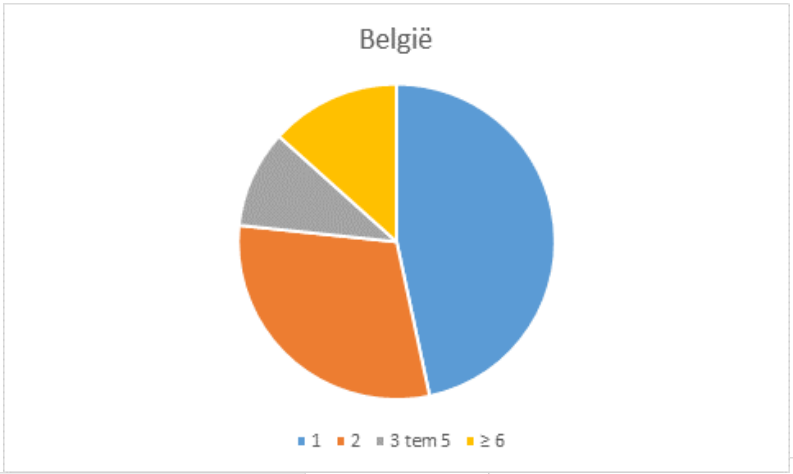
TISSUE BANK	97
INTERMEDIARY STRUCTURE	25
PRODUCTION ESTABLISHMENT	3

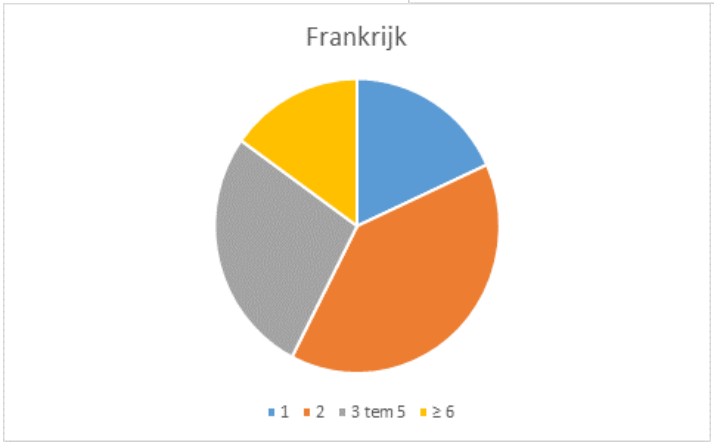
Authorised tissue banks per tissue/ cells

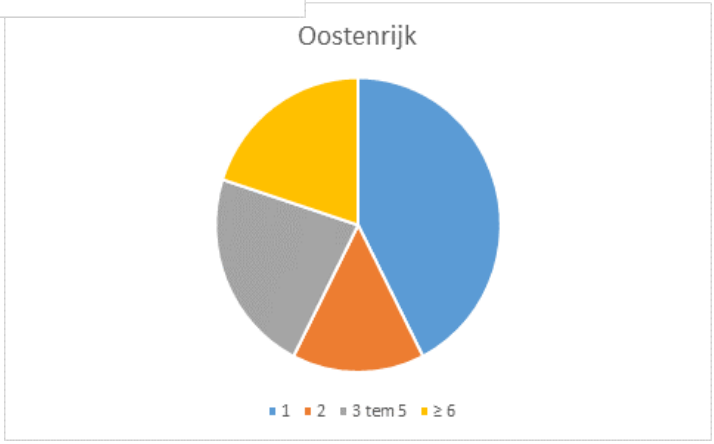


Distribution of authorised tissue banks /hospital

BE: 79 TB/20 hospitals; several = multitissue banks: 1 HBM manager and 1 quality system







Advisory report 9335 Superior Health Council Belgium 2017

Number "*tissue establishments for replacement tissue*"

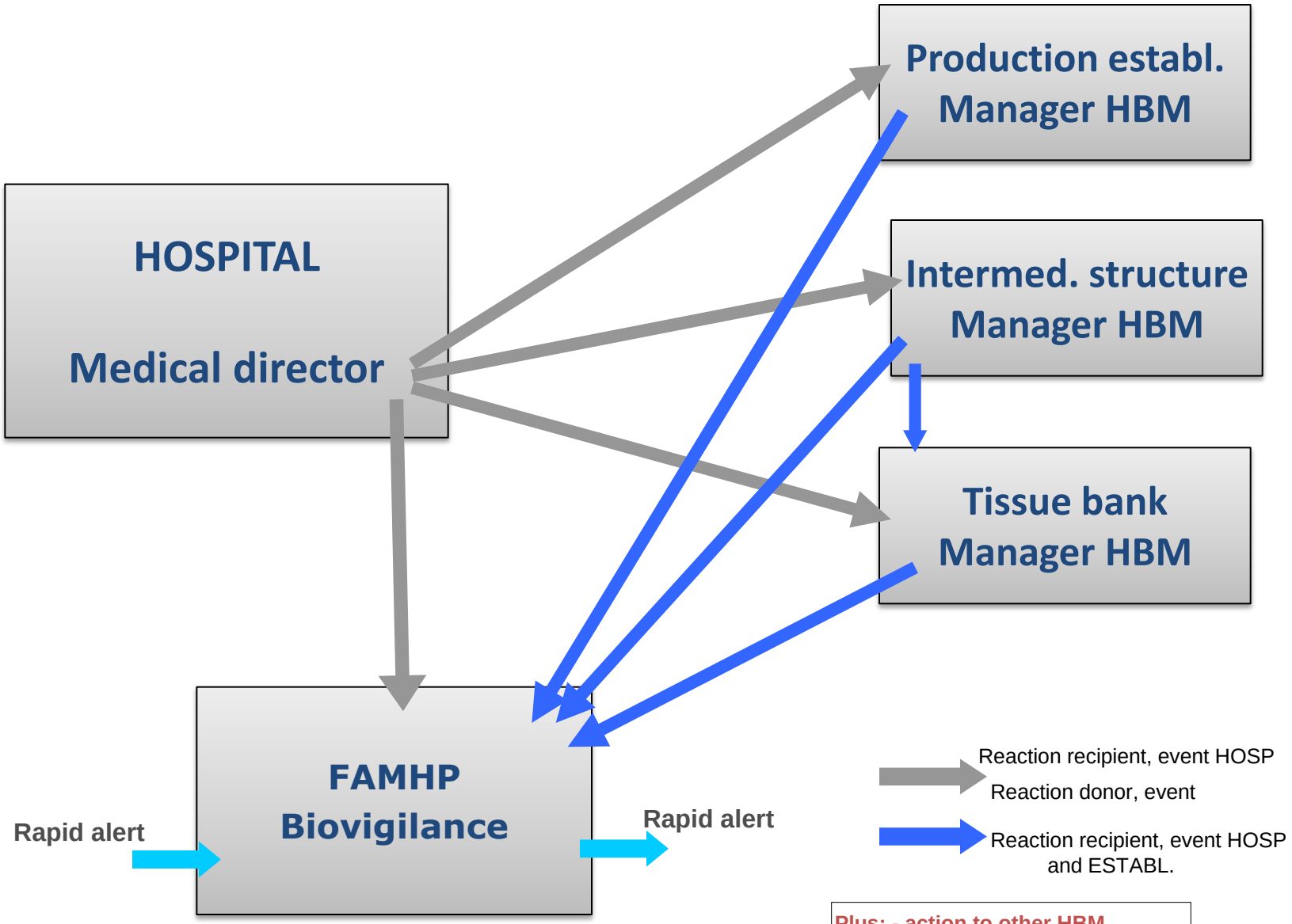
	AT	BE	DE	FR	NL	UK
N° of tissue establishments (TEs) for replacement tissues (number of multitissue banks)	28 (17)	42 (0*)	154 (10)	76 (16)	33 (5)	65 (41)
Cardiovascular	*1*	*1*	*6*	*14*	*1*	*3*
Musculo-skeletal	*7*	*14*	*119*	*26*	*27*	*45*
Ocular tissues	*5*	*4*	*24*	*17*	*2*	*3*
Skin	*1*	*3*	*2*	*10*	*1*	*2*
Other	*26*	*21*	*71*	*17*	*4*	*53*
Inhabitants (mio)	9	11	81	66	17	65

*20 possible

Economic landscapes of human tissues and cells for clinical application in teh EU, 2015

Bijlage 3: Vergelijking van de meer gedetailleerde gegevens voor België, Frankrijk en Oostenrijk Bron: verwerkte data gebaseerd op gegevens van: FAGG (www.fagg-afmps.be), ANSM (www.ansm.santé.fr) en BASG/AGES (www.basg.gv.at).

	BELGIE 17-02-2016			Per 1 mio inw	Frankrijk 01-07-2016	Per 1 mio inw.	Oostenrijk 06-07-2015	Per 1 mio inw
	Bank	Intermed productie structuur	Totaal instelling					
Locomotorisch stelsel	7		7	0,6	17	0,3		3,4
Locomotorisch – bot							16	
Locomotorisch – kraakbeen							9	
Locomotorisch - pezen							6	
Locomotorisch stelsel (beperkt tot femurkoppen en / of schedelluiken)	7		7	0,6		0,3		3,4
Femurkoppen					21		17	
Schedelluiken							14	
Tympano-ossiculaire weefsels	4		4	0,4		0,0		0,0
Amnionmembranen nos				0,4	18	0,3	8	0,9
Amnionmembranen	1		1					
Placentaire vliezen	1		1					
Amnionmembranen voor oftalmisch gebruik	2		2					
Huid	4		4	0,4	9	0,1	8	0,9
Keratinocyten	3		3	0,2	2	0,0		0,0
Oftalmische weefsels	4		4	0,4	16	0,2	7	0,8
Bloedvaten nos				0,4	13	0,2	2	0,2
Bloedvaten	3		3					
Bloedvaten (venen)	1		1					
Hartkleppen	2		2	0,2	7	0,1	3	0,3
Hematopoiëtische stamcellen en donor lymfocyten voor infusie	13		13	1,9		1,1		5,7


Production establ.
Manager HBM
HOSPITAL
Medical director
Intermed. structure
Manager HBM
Tissue bank
Manager HBM
FAMHP
Biovigilance
Rapid alert
Rapid alert
Reaction recipient, event HOSP
Reaction donor, event
Reaction recipient, event HOSP
and ESTABL.
Plus: - action to other HBM
- storage data (proc.)

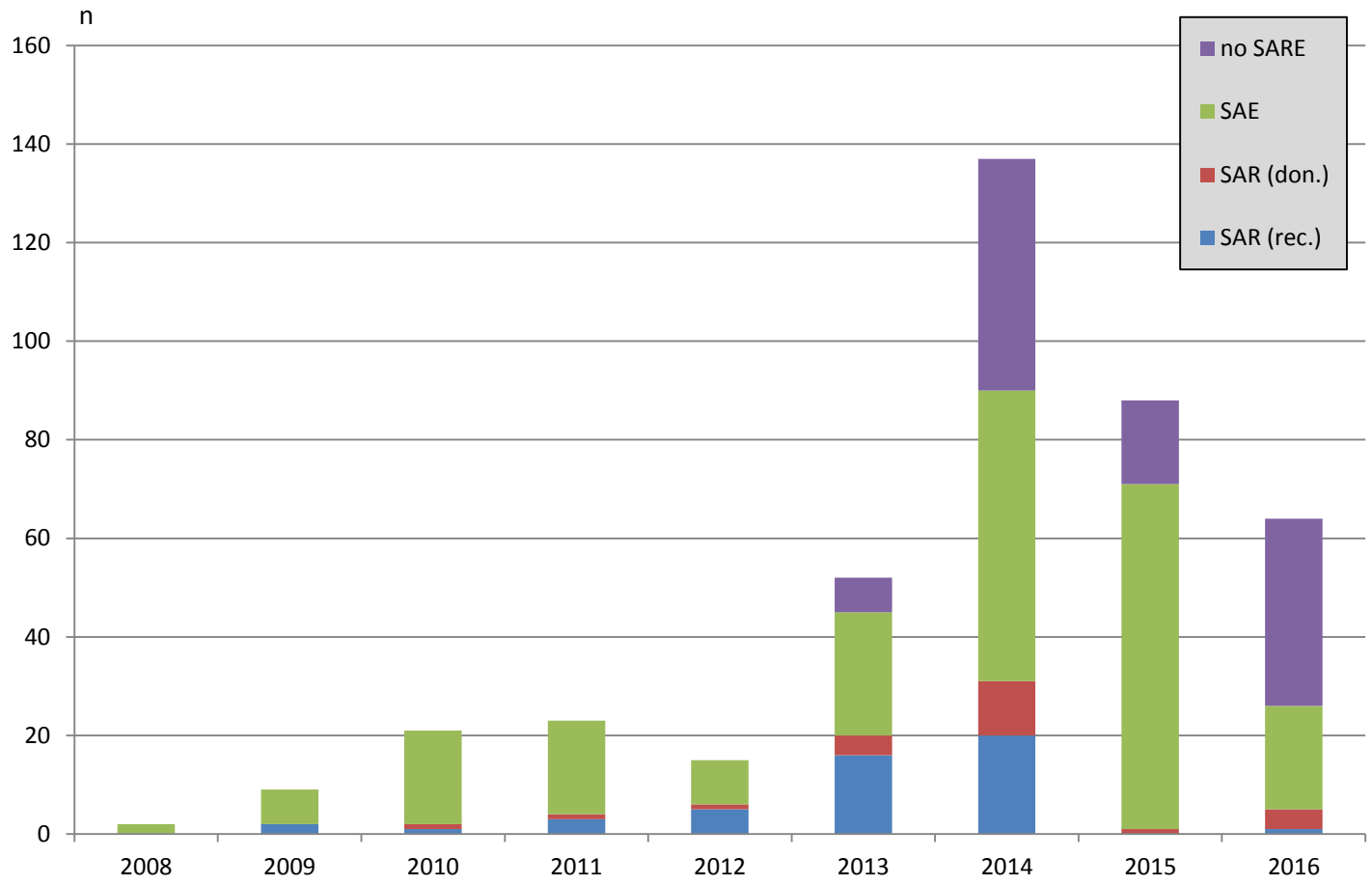
Tissues and cells: distributed in 2016 (1/2)

TYPE HBM	Unit	Total
Musculoskeletal tissues (total)	n	14.709
Amnion membranes – ocular use	n	107
Placenta membranes (amnion and chorion)	cm^2	1.901
Ocular tissues	n	1.098
Tympano-ossicular tissues	n	387
Heart valves	n	294
Vessels	n	185
Venous allografts	cm	2.102
Skin	cm^2	197.133
Keratinocytes	cm^2	45.700

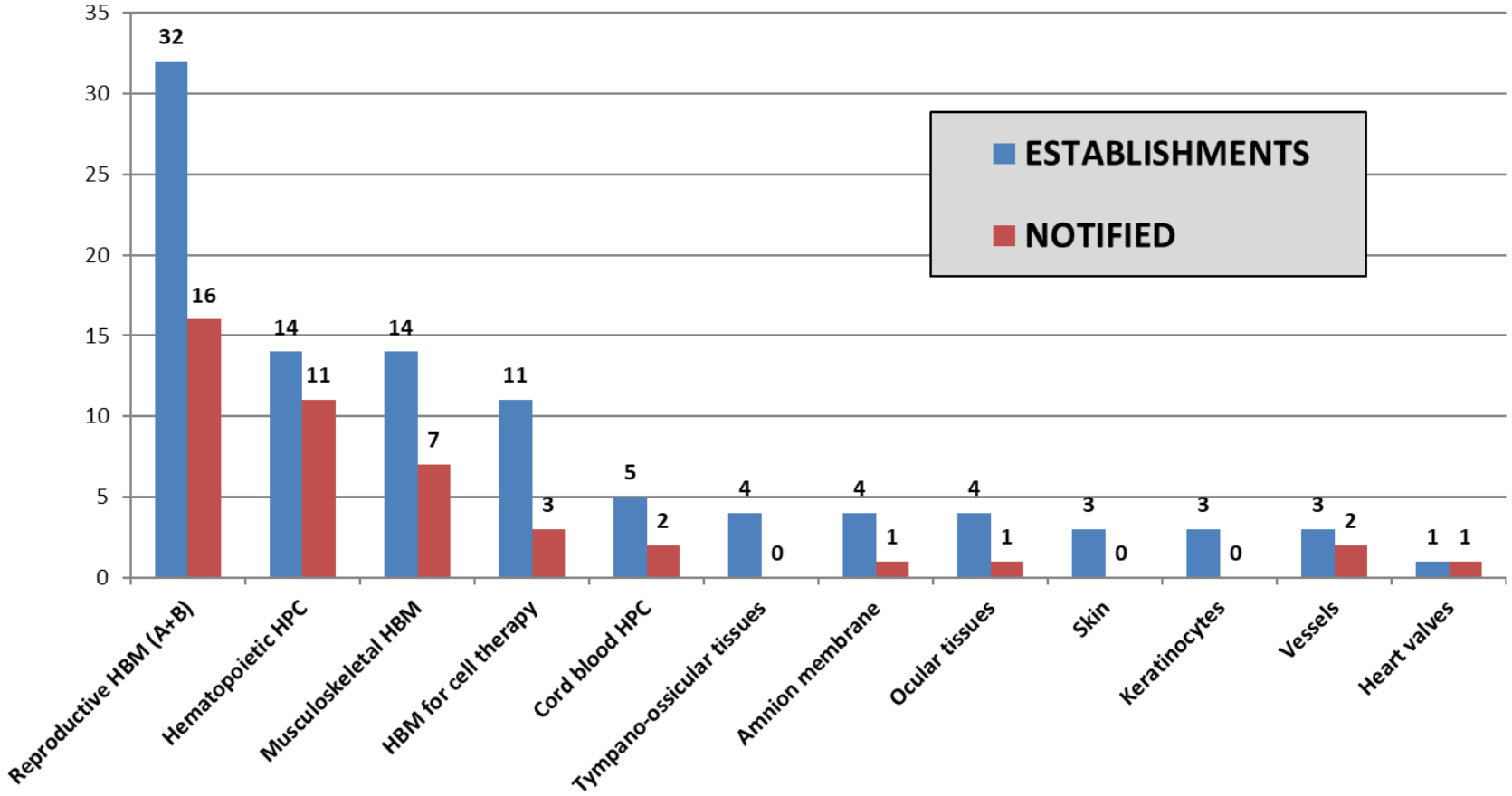
Tissues and cells: distributed in 2016 (2/2)

TYPE HBM	Unit	Totaal
Hematopoietic progenitor cells: total	bag	2.108
- cord blood	n	*20*
- bone marrow allo	n	*60*
- bone marrow auto	n	*4*
- periph blood allo	bag	*518*
- periph blood auto	bag	*1.365*
Lymphocytes for infusion (DLI)	bag	141
Embryos	n	37.223
Gonades and gonade fragments	n	394
Capacitation of male gametes for IUI	n	23.137

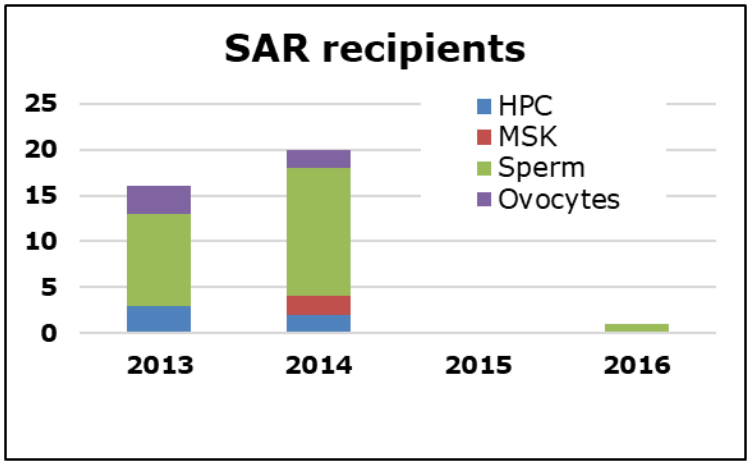
Biovigilance notifications received (2008-2016)

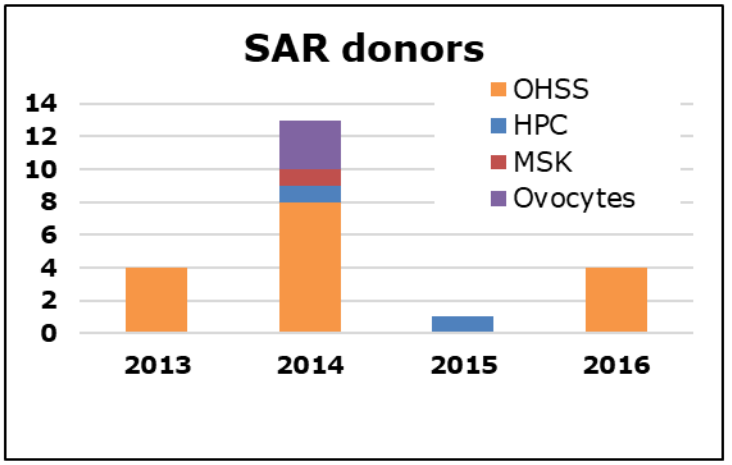


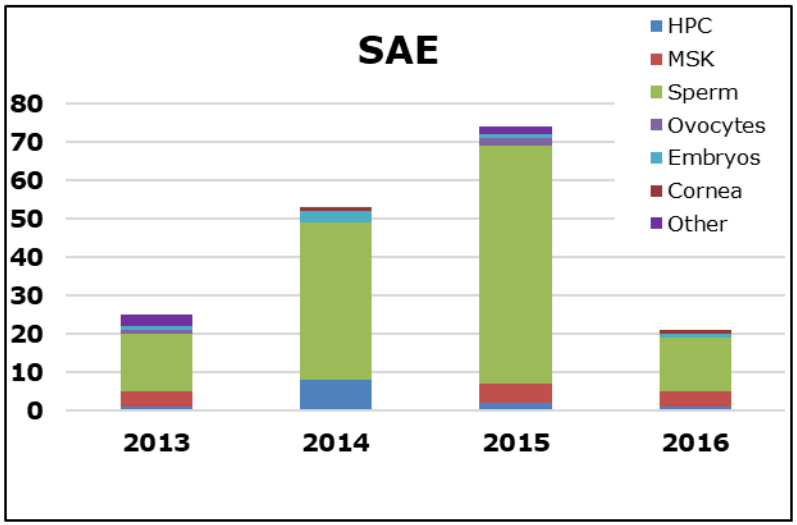
Notifications by banks for HBM (2008 – 2016)



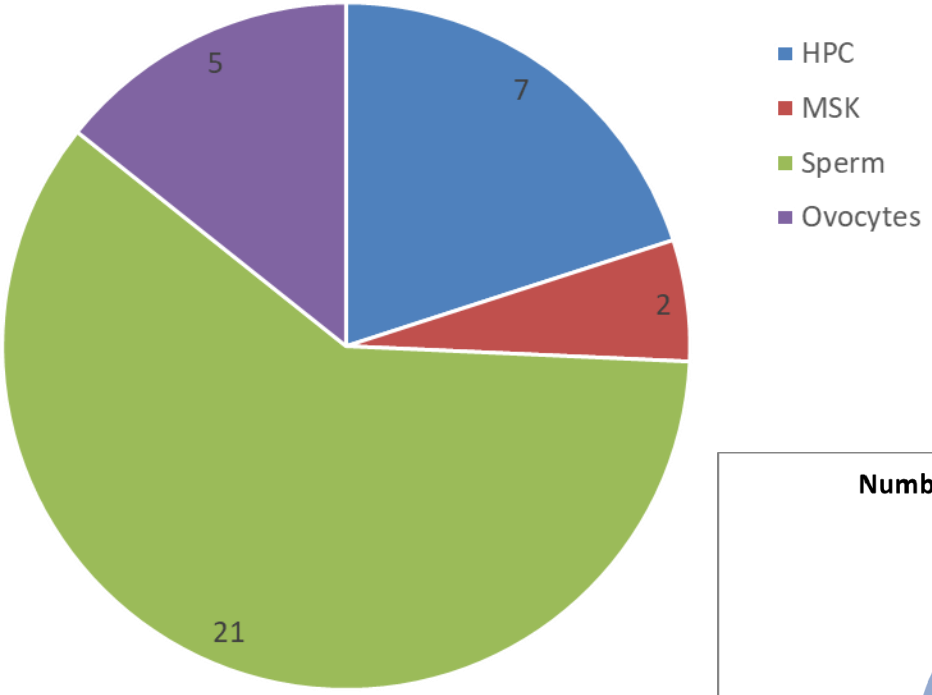
SAR and SAE (2013-2016)

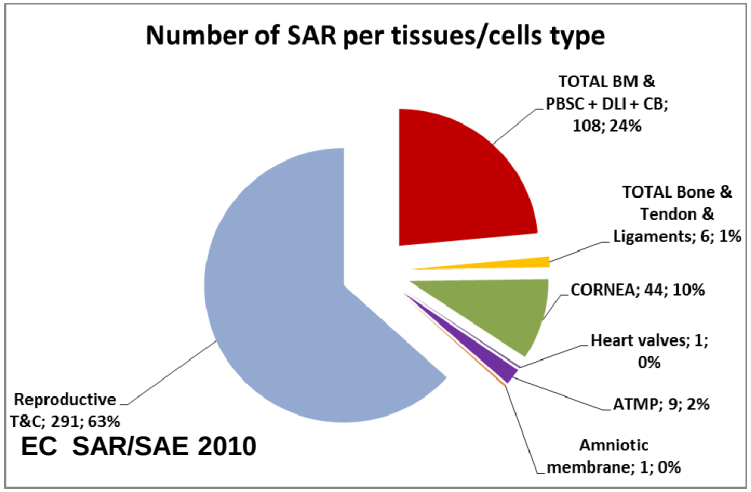






SAR recipients 2010 - 2016





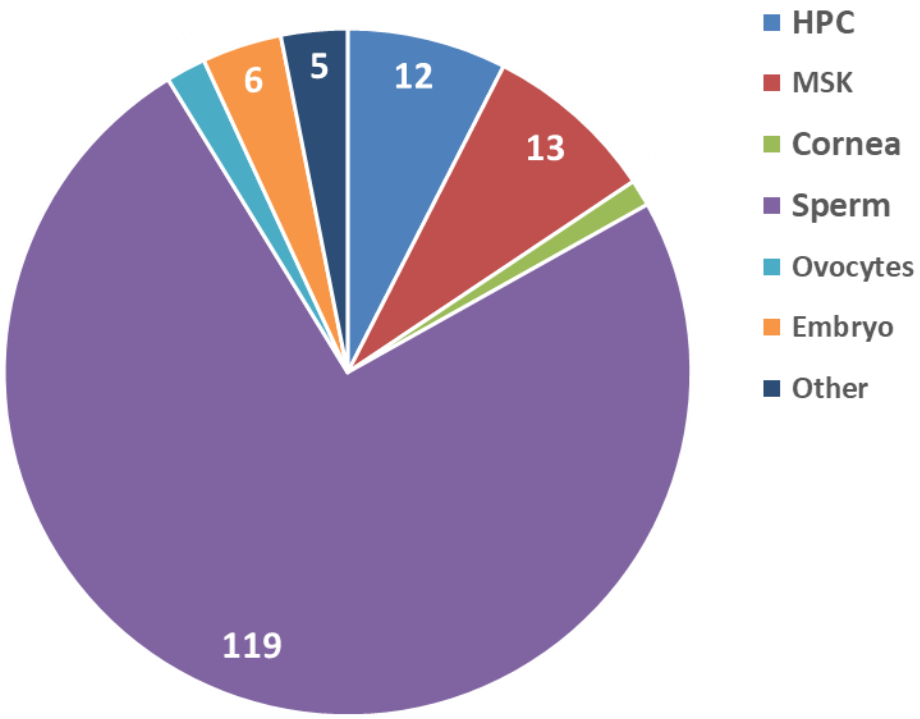
SAR in recipients (2010 - 2016

W/C TYPE	n	BIJWERKING
Sperm	1	*Foetal anomaly: hypoplasia left heart*
	2	*Transfer genetic disease: Multipele Endocriene Neoplasie Syndroom (MEN-1)*
1	3	*Transfer genetic disease: neurofibromatosis (NF1)*
Ovocytes	1	*Achondroplasia*
HPC	1	*MDS REAB with trisomy 8 of donor origin developed 2,5 years afterTRP*
HPC	1	*Neurological toxicity : epileptic crisis*
HPC	1	*Alleafter HPC TRP1,5 hrs rgic reaction*
HPC	1	*Toxicity: serious hypotensie*
HPC	1	*Hemolytic non immunologic reaction*
HPC	1	*Hypotension*

SAR in donors 2010-2016

W/C TYPE	n	SAR
MNC	1	*Hypotension after stop apheresis*
Cartilage	2	*Hemarthrosis*
Cartilage	1	*Deep venous thrombosis*
HPC	1	*Spleen rupture after stem cell mobilisation (Neupogen)*
HPC	1	*Arterial punction (unrelated donor)*

SAE (2012-2016)



Summary

1. SHC advice 9335: rationalisation possible by moving from separate TB to multitissue banks (1 manager HBM, 1 quality system).
2. Clinicians notify to TE, not to competent authority.
3. Reproductive HBM: most notifications.
4. Info on birth of a child with a genetic disease following ART with non-partner gametes or donated embryos to the concerned fertility centre is important.
5. Effect on notifications by ditribution of specific guidelines. Effect does not last for years.
6. RATC system has proven its value. .

Thank you