

Reporting of SAE and SAR in France

*Agence française
de sécurité sanitaire
des produits de santé*

***French health
products safety
agency***



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Haemovigilance in France



Haemovigilance network

Ministry of Health

National

Afssaps

InVS

EFS and
CTSA

Haemovigilance
national committee

Donors epidemiology

Regional

Regional blood
establishments:
17 HvC

RHC: 24
Regional
haemovigilance
coordinators

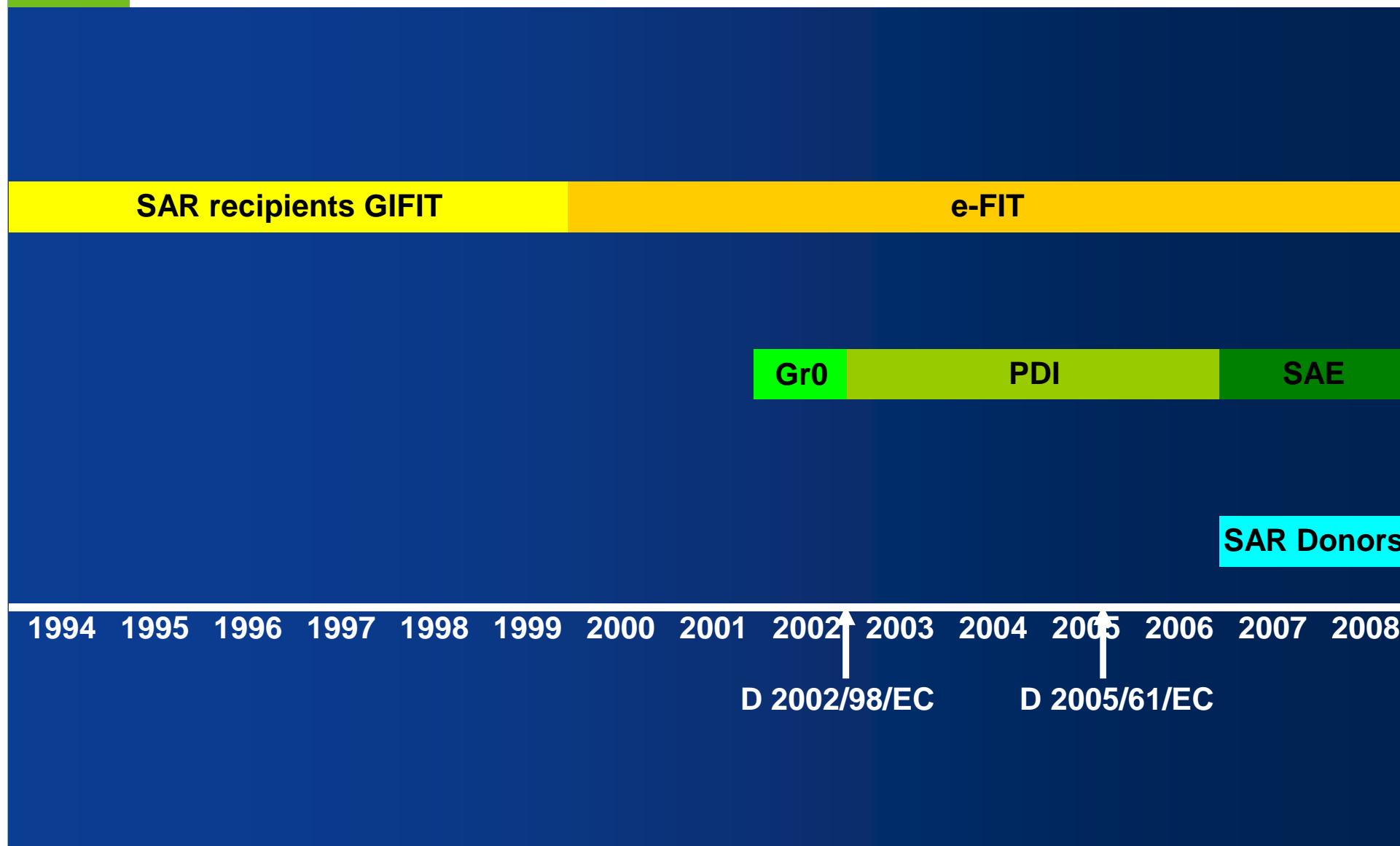
Local

Local blood
centers: 150
HvC

Hospitals and hospital
blood banks:
1600 HvC, TC

Healthcare professionals

Time table of the implementation of EU Directives in France



How to notify of AR in recipients ?



8 h

Healthcare professionals

Reporting

**Haemovigilance
correspondent
HE**

Form filling in

**Haemovigilance
correspondent
BE**

**Data capture on
web-site e-FIT**

48 h

Notification

15 d

Afssaps

EFS / CTSA

**Regional
haemovigilance
coordinators**

MoH

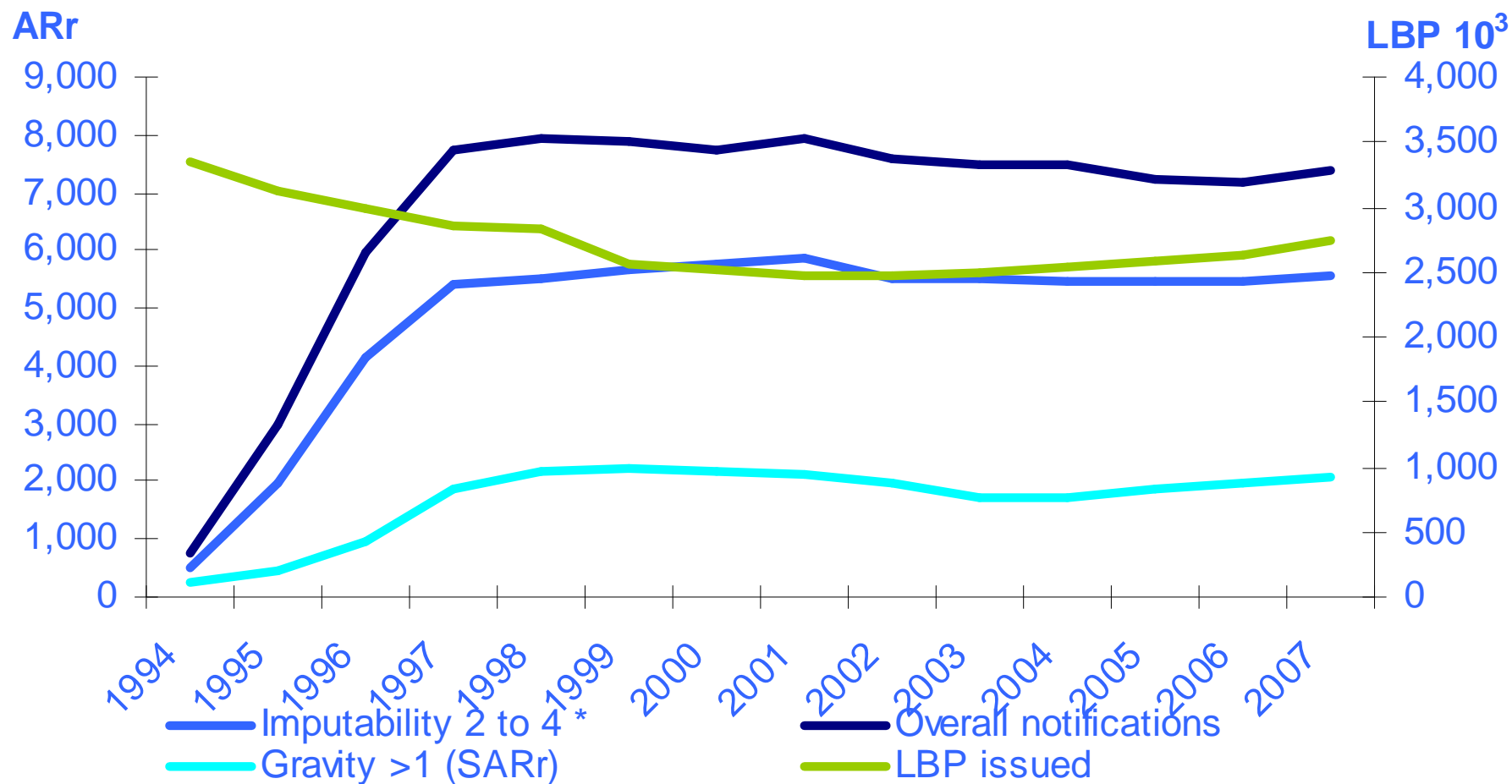
Regional prefect

Of what SARr is the Afssaps notified ?



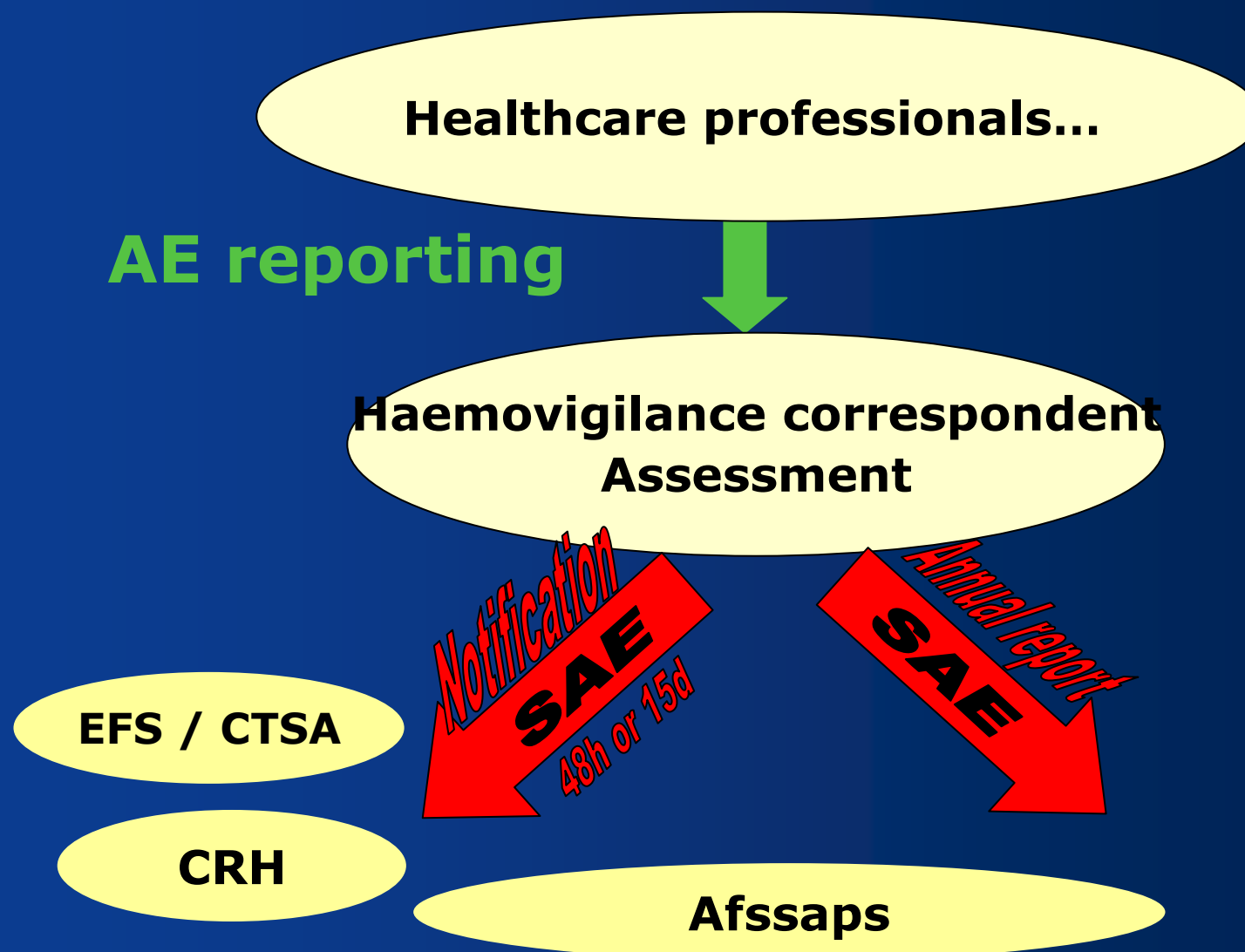
2000 - 2007	AR	AR per 10,000 LBP	SAR	SAR per 10,000 LBP
Imputability 0 to 4	60,061	29.34	15,630	7.64
FNHTR	20,972	10.24	175	0.09
Allergy	12,185	5.95	372	0.18
AHTR (ABO)	140	0.07	38	0.02
AHTR (other)	2,236	1.09	213	0.10
DHTR	11,946	5.84	11,630	5.68
TACO	1,763	0.86	613	0.30
TTBI	1,511	0.74	165	0.08
TTVI	848	0.41	831	0.41
TRALI	196	0.10	137	0.06
UCT	5,904	2.88	477	0.23

Notification of SARr 1994 - 2007



* French scale, ≥ 1 EU scale

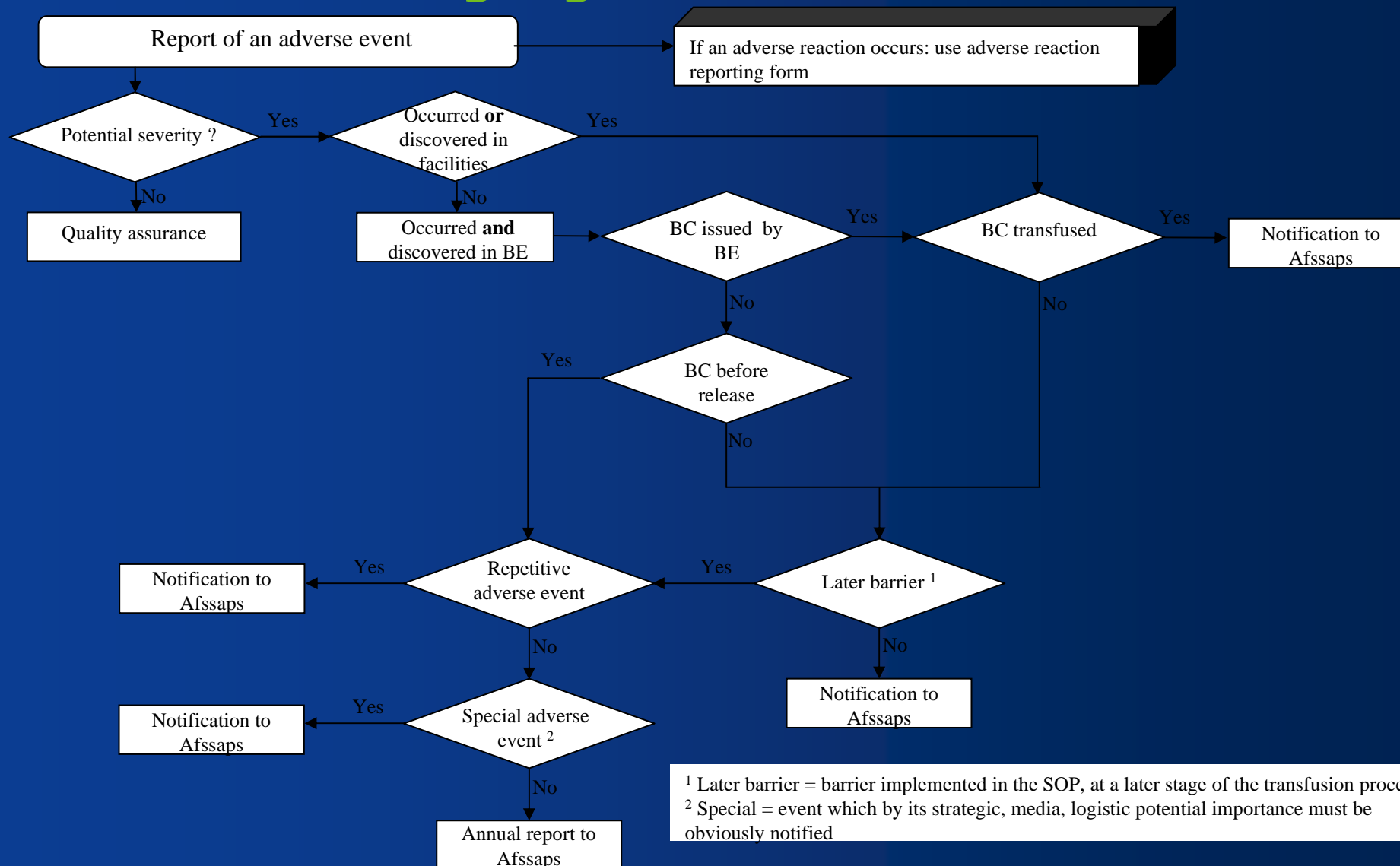
How to notify of SAE ?



Of what SAE is the Afssaps notified ?



Decision-making algorithm



Notification of SAE in 2007

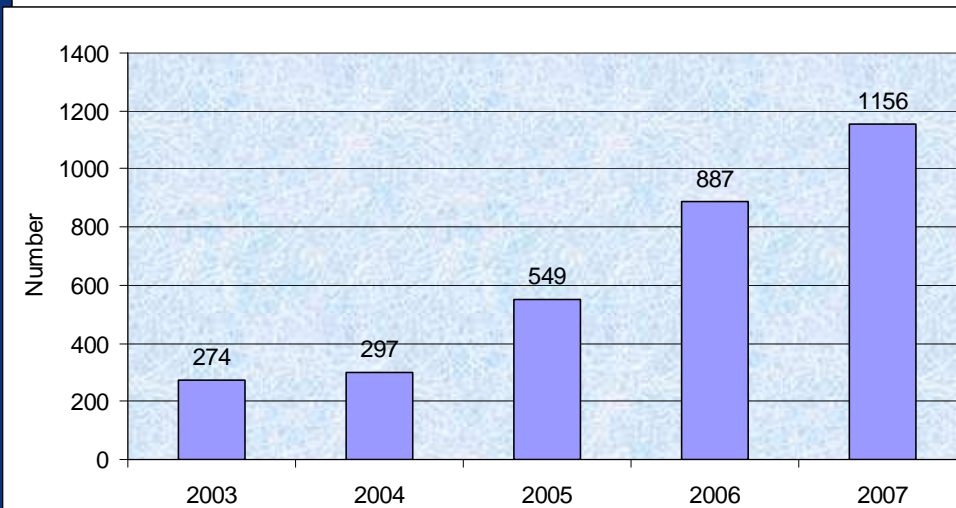
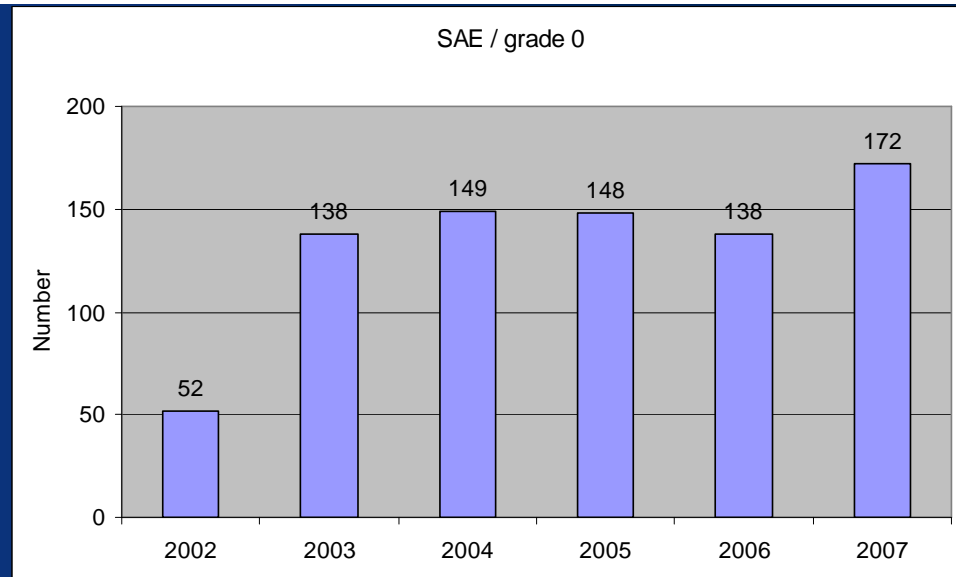


- 43 SAE without transfusion (blood components not transfused) :
 - **17 SAE related to the laboratories** : 7 errors of patient identification, 10 errors related to group and phenotype determination
 - **14 SAE related to blood components issuing** : 11 errors of patient identification, 3 issuing errors (blood components issued to wrong patients)
 - **4 SAE due to erroneous patient data in IT system**
 - **3 breakdown of blood components storage equipment**
 - **3 delay in transport** of blood components and/or samples for laboratory analysis
 - **1 error in linking donor with appropriate donation**
 - 1 Other

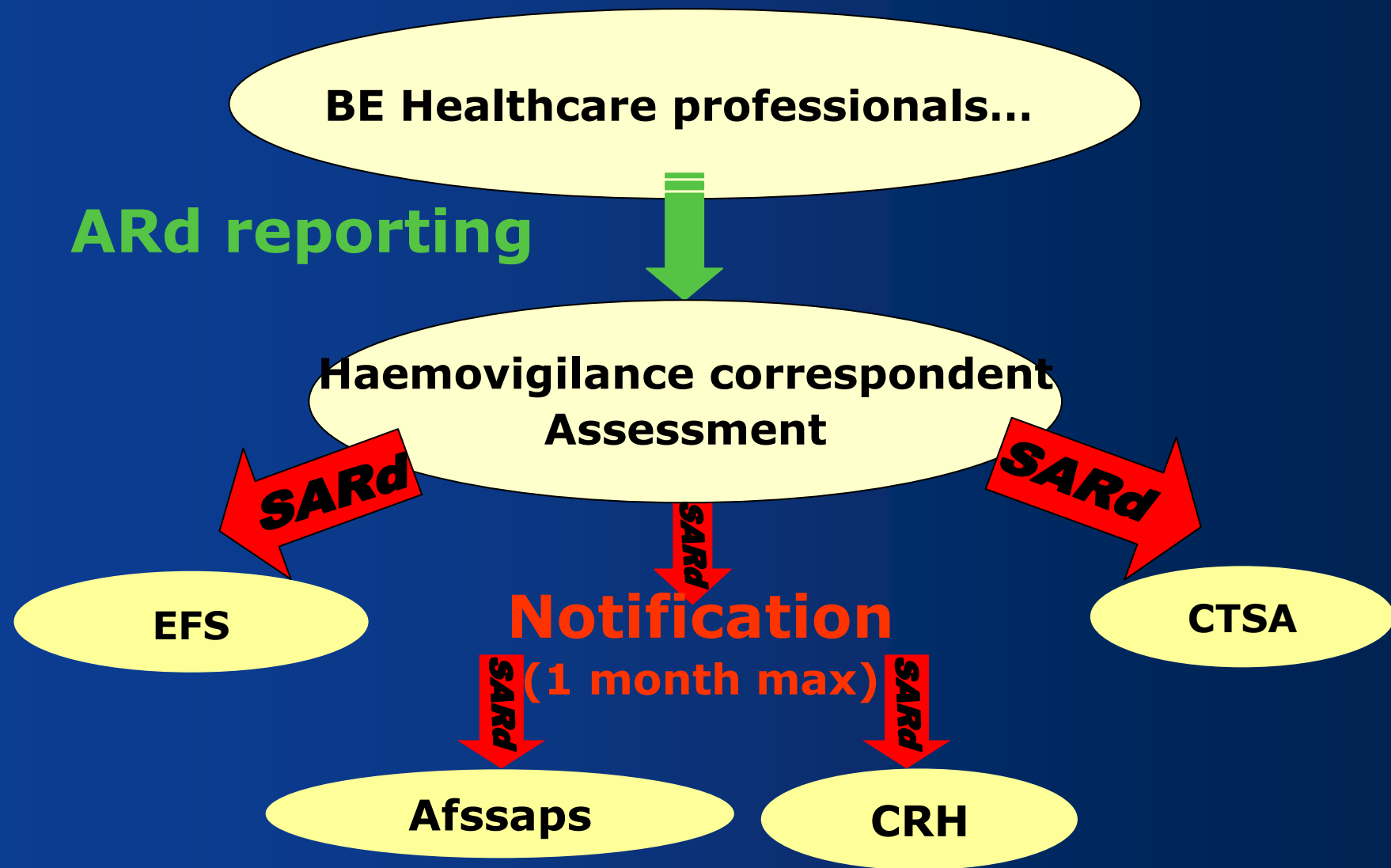
Notification of SAE before 2007



- Grade 0:
IBCT without
clinical/biological
sign
- Post donation
information (PDI)



How to notify of SAR in donors ?



Of what SARd is the Afssaps notified ?



A serious adverse reaction in donor (SARd) is an unintended response associated with the collection of blood or blood components that is fatal, life-threatening, disabling, incapacitating, or which results in, or prolongs hospitalization or morbidity

- **Serious:**

- Medical intervention outside the blood center
- Hospitalization of the donor
- Death of the donor

- **Imputability:** same scale as the EU Directive for serious adverse reactions in recipients

Notification of SARd in 2007



296 notifications

(6 not assessable)

	Nb of donors
Local reaction	106
General reaction	168
General and local reaction	16
Total	290

Nb of donors	Whole blood	Apheresis	Total
Medical intervention	143	62	205
Hospitalization	63	22	85
Total	206	84	290

Thank you for your attention

Heamovigilance unit – Afssaps – France

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