

# Implementation of the EU Directive: Consequences on the French haemovigilance system

*Agence française  
de sécurité sanitaire  
des produits de santé*

*French health products  
safety agency*



**Cyril CALDANI, MD**  
**Head of haemovigilance unit**

9<sup>th</sup> EHS – Dublin 2007

# Before the Directive



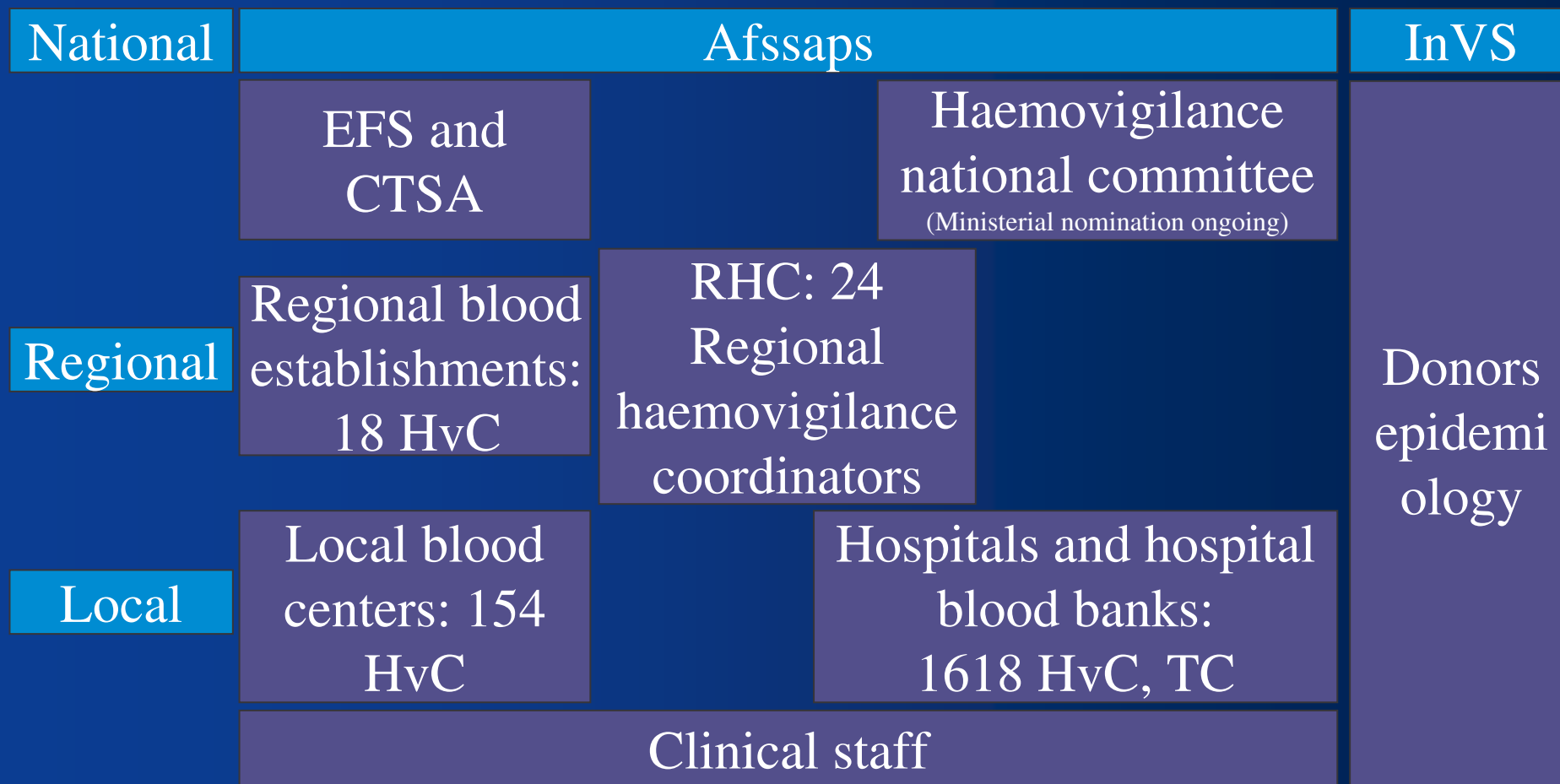
- **National haemovigilance system in place since 1994**
- **National authority = Afssaps (French health products safety agency)**
- **Haemovigilance network = regional coordinators (CRH) and haemovigilance correspondents in hospitals and blood centers**
- **French national blood service (EFS) and Army blood centre (CTSA) product LBP**

# Haemovigilance in France 2000 - 2006



## Haemovigilance network

Ministry of Health



# Before the Directive



- **Notification of**
  - ✓ all adverse transfusion reactions, mandatory whatever the degree of severity
  - ✓ IBCT without adverse reaction
- **Procedure in place in blood establishments and hospital blood banks to withdraw from distribution and issuing blood or blood components associated with a notification**
- **Post donation information**
- **Donors epidemiology**

# Before the Directive

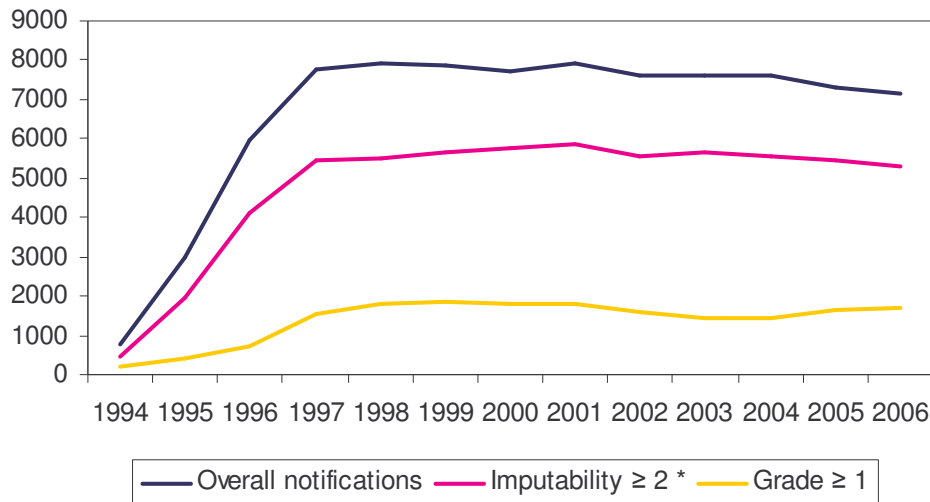


- **Traceability system in place in blood and health care establishments**
- **Records of data on traceability retained 40 years**
- **Unique identifiers**
- **Annual reports by Afssaps**
- **Regulations and guidance published (TTBI, TRALI, practical carrying out of blood transfusion )**

# Haemovigilance in France 1994 - 2006

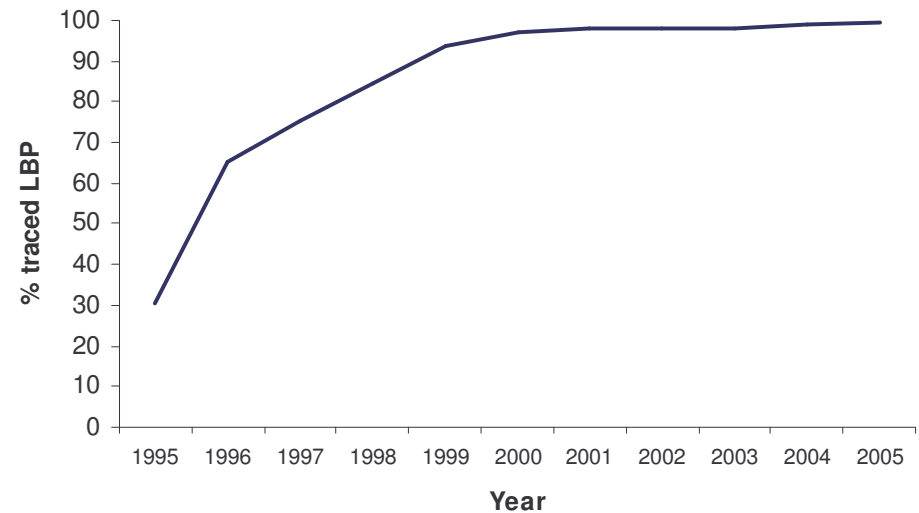


## Notification of ATR



\* French scale,  $\geq 1$  EU scale

## LBP traceability





# After the Directive



- **Competent Authority = Afssaps**
- **No change to notification of adverse reactions in recipients**
- **Records of data on traceability retained 30 years**
- **Annual report submitted by Afssaps to the Commission by 30 June (2007 ?)**

- **Implementation of the notification of serious adverse reactions in donors**
  - Mandatory
  - 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
- **Afssaps regulatory framework to be finalized (2007)**

# After the Directive



## FICHE DE DECLARATION D'EFFET INDESIRABLE GRAVE DONNEUR

### 1. Numéro de la Fiche :

Code ETS    Année    Code site    N° effet indésirable 4 chiffres + 1 lettre

### 2. Etablissement préleveur :

ETS : .....  
 Site : .....  
 Type de collecte :  
 Site fixe  
 Collecte mobile

### 3. Donneur :

Date de naissance : / /    M    F    Poids : .....  
 Premier don  
 Premier don pour ce type de don  
 Donneur connu

### 4. Type de don en relation avec la survenue de l'effet indésirable grave :

Sang total  
 Aphérese plasmatique  
 Aphérese plaquette flux continu  
 Aphérese plaquette flux discontinu  
 Aphérese combinée, préciser : .....  
 Erythrapèse

### 5. Circonstances de survenue :

Date du don : / /  
 Lieu de survenue :  pendant le prélèvement  
 Après le prélèvement / (jours) / (h) / (min)  
 Sur le lieu de prélèvement  
 Bien dehors du lieu de prélèvement, préciser : .....

### 6. Gravité :

Grade 2 (prescription d'une consultation extérieure)  
 Grade 3 (hospitalisation)

### 7. Manifestations cliniques :

<b>LOCALES</b>	<b>GENERALES</b>
<input type="checkbox"/> Hématome	<input type="checkbox"/> Malaise vagal
<input type="checkbox"/> Réaction allergique	<input type="checkbox"/> Perte de connaissance
<input type="checkbox"/> Réaction inflammatoire	<input type="checkbox"/> Hypotension majeure
<input type="checkbox"/> Infection point de piqûre	<input type="checkbox"/> Crise de tétanie
<input type="checkbox"/> Blessure artérielle	<input type="checkbox"/> Convulsions
<input type="checkbox"/> Blessure nerveuse	<input type="checkbox"/> Crise Angor, IDM, arythmie
<input type="checkbox"/> Autres, préciser : .....	<input type="checkbox"/> Embolie gazeuse
.....	<input type="checkbox"/> Réaction allergique générale
.....	<input type="checkbox"/> Autres, préciser : .....
.....	.....

### 8. Complication (s) de l'effet indésirable grave initial :

Oui     non

### 9. Dysfonctionnement associé :

Oui     non  
 Si oui, description : .....

### 10. Compléments d'information :

Antécédent d'effet indésirable grave     oui     non  
 Don interrompu     oui     non  
 Volume prélevé (si pertinent) : ..... (Unités ml)

Description et précisions concernant l'effet indésirable grave :  
 .....  
 .....

Traitement instauré, prise en charge : .....

Antécédents donneur (pathologies, traitements éventuels) :  
 .....

Commentaires :  
 .....  
 .....

### 11. Imputabilité :

non évaluable  
 0 (exclus, improbable)  
 1 (possible)  
 2 (probable)  
 3 (certain)

Date de la déclaration : / /

Nom et signature du correspondant ETS : .....

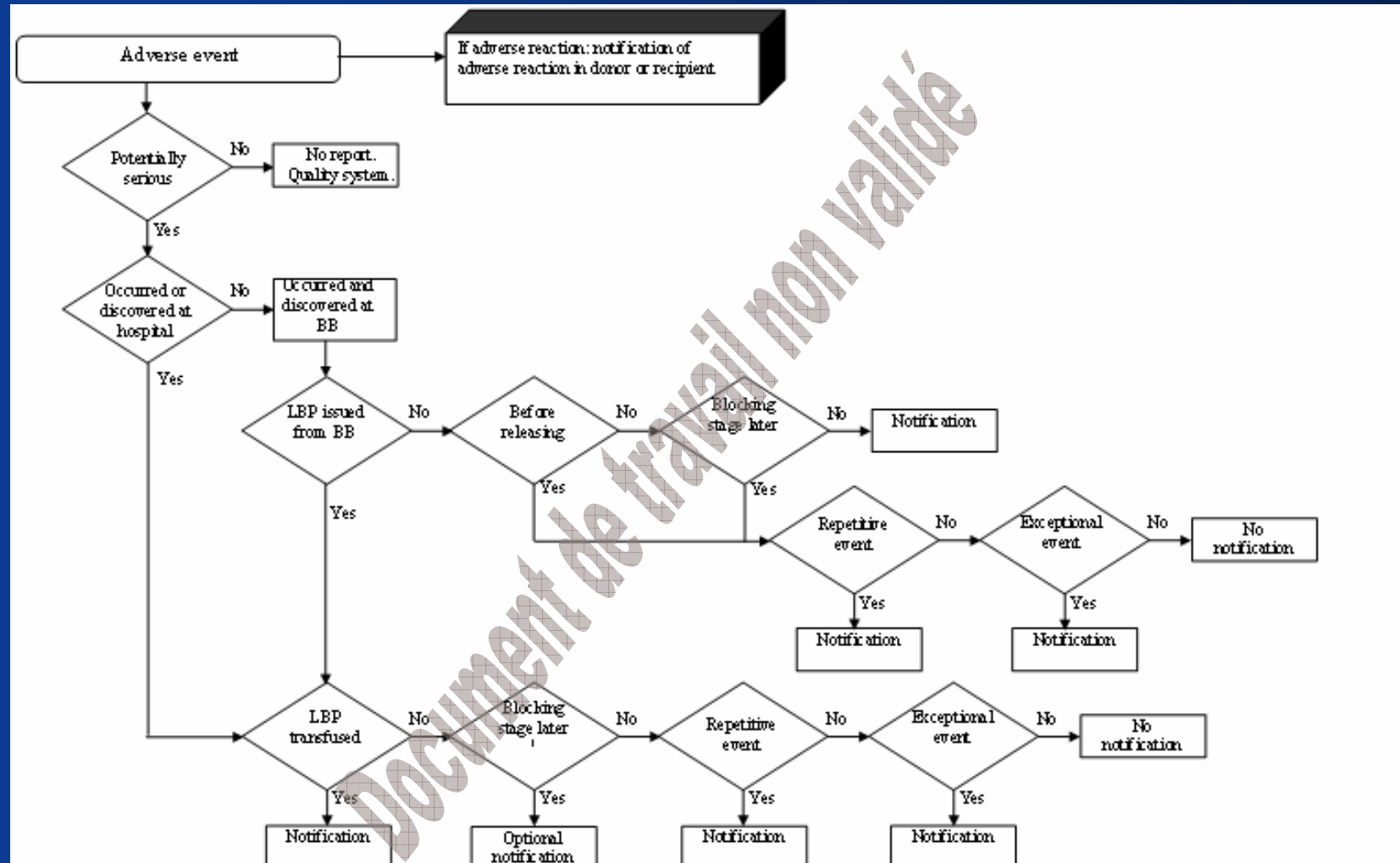
Document de travail non validé

Document de travail non validé

- **Implementation of the notification of serious adverse events by blood establishments, hospital blood banks and health care establishments**
  - Mandatory
  - Serious = decision-making algorithm:
    - Distinction between haemovigilance and quality system
    - Potential gravity
    - Frequency of the event
  - Imputability: not relevant
  - Annual report
- **Afssaps regulatory framework to be finalized (2007)**

# After the Directive

## Decision-making algorithm





- **Evaluation after 2 or 3 years of implementation**
- **Possible extension of the on-line notification**

# After the Implementation



**Thank you for  
your attention**

