CENTRO NAZIONALE SANGUE

Istituto Superiore di Sanità

Road to 2027 within the Blood field: The French action plan

Dr Imad SANDID

French National Agency for Medicines and Health Products Safety (ANSM)

Rome, April 8th 2025

Disclosures

No conflict for interest to declare

Gap analysis: current situation → 2027_1

- Presentation of the new SoHO regulation to different stakeholders (SoHO Competent Authorities, Regional Competent Authorities, Hospitals, Clinics etc…).

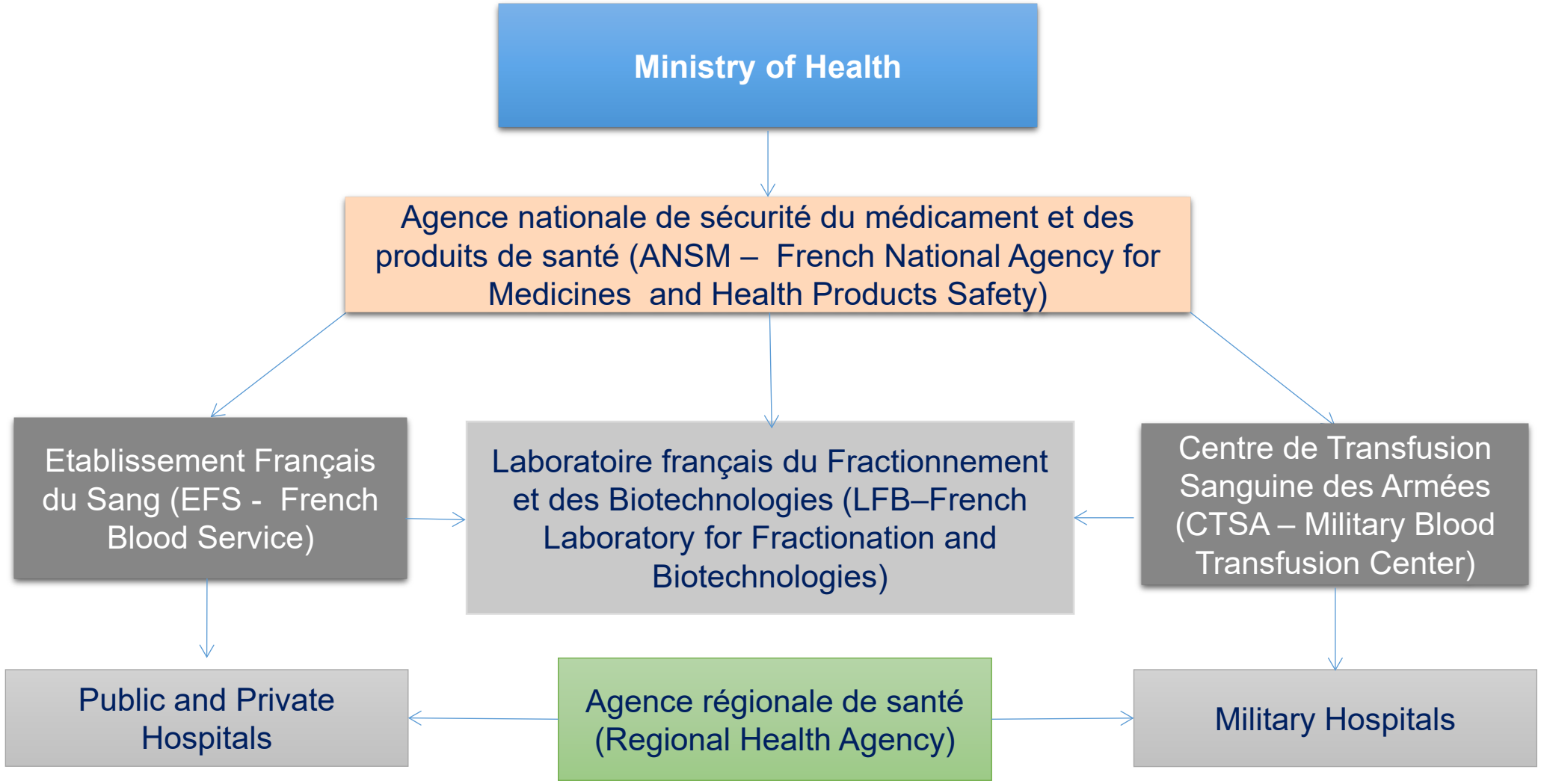
- Setting up of national working groups (WG):
  - ✓WG for definition of criteria for “critical SoHO preparations”,
  - ✓WG for definition of criteria for “critical SoHO entities”,
  - ✓WG for definition of criteria for establishing “national emergency plans”.

- We have identified different systems and different competent authorities (CAs) depending on the SoHO categories. This will require a lot of efforts (human, financial, regulatory and communication with stakeholders) to prepare for the implementation of the SoHO regulation in 2 years.
- The main tasks concern the application of the requirements of the new regulation to facilities (hospitals and clinics).

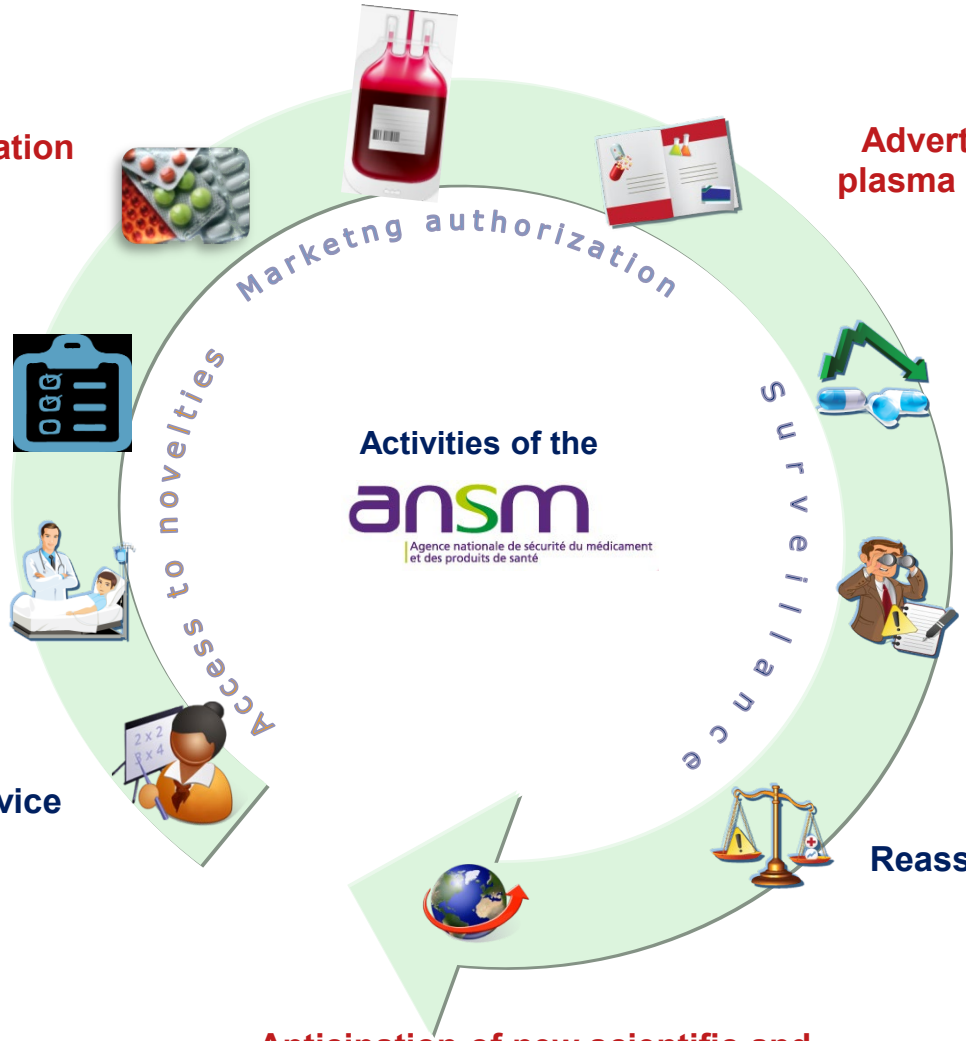
Gap analysis: current situation → 2027_2

- Mapping of SoHO activities to discuss ways how to prepare implement the new SoHO Regulation:
  - ✓ reorganization of SoHO competent authorities (national and regional) to optimize operations and communications with the NCA,
  - ✓ adaption of existing procedures or introducing new elements such as communication and the SoHO preparation authorization system.
  - ✓ adapting inspection, vigilance, and authorization procedures,
  - ✓ establishing national emergency plans,
  - ✓ modifying national legislation,
  - ✓ setting procedures for the national classification status of SoHO/products in accordance with the SCB's opinions/work.

Interaction between the main actors involved in the blood system in France



Life cycle of Blood & Blood Components at the ANSM



Evaluation, authorization and registration of new blood components

Import authorization

Advertising Authorization (for plasma intended for transfusion)

Development and updating of the standard document Pre-donation Questionnaire

Authorization and inspection of blood establishments and external quality controls

Clinical trial authorization

Haemovigilance (Donor and Recipient Adverse reactions, Serious adverse events, Post-donation Information, and denominators) + Vigilance of medical devices + Vigilance of IVD used in transfusion chain

Scientific Advice

Reassessment of the benefit-risk ratio

Anticipation of new scientific and regulatory challenges

Key data on transfusion activity in France 2023

~ 1 600 000
Blood Donors

~2 600 000
Blood and Blood components donations

- ~ 3.5% of the population aged 18 to 65
- ~ 52% women
- ~ 17% first time donors
- ~ 85% WBD
- ~ 15% Apheresis donations
  - ✓ ~ 12% plasmapheresis
  - ✓ ~ 3% platelpheresis

~ 190 SAR donors
- ✓ ~ 69% VVR
- ✓ ~ 6% MCE

~ 2 800 000
Blood components (BC) distributed/issued

- ~ 80% Red cells
- ~ 12% Platelets PR
- ~ 8% FFPq/FFP PR

Traceability: 99.1%
Wastage: 0.73%.

~1 300 Transfusing facilities (hospitals & clinics) ~ 750 SAR reporting facilities
~ 150 SAR

~2 blood establisments
~ 207 sites:
- ✓ 152 blood collection fixed sites
- ✓ 145 blood distribution sites
- ✓ 18 blood processing sites
- ✓ 8 blood donation testing laboratories

~ 40,000 blood mobile collection sessions

~525 000
patients transfused

- ~ 5 BC transfused / patient
- ~ 8 patients transfused / 1000 inhabitants
- ~ 39 BC transfused / 1000 inhabitants

~2 600 000
BC transfused

- ~ 80% Red cells
- ~ 12% Platelets PR
- ~ 8% FFPq/FFP PR

Mapping of the blood activities_1

Blood donors registration

- **NCA (ANSM)** is in charge of the definition of a national coding system for unique blood donor identifying number and unique blood donation identifying number.
- **Blood establishments** (BE) are in charge of their donors registers.

Blood donors history & medical examination

- **NCA** is in charge of the definition of donor eligibility criteria & standard document pre-donation questionnaire & the inspection of BEs.
- **BEs** are in charge of the implementation of donor selection criteria in accordance to the national/european legislation.

Blood collection

- **NCA** is in charge of the authorization and the inspection of the blood collection activity (fixed sites and mobile collection sessions), including the plasma donations intended for fractionation.

Blood donors/donations testing

- **NCA** is in charge of the authorization and the inspection of the blood donors/donations testing laboratories, including the plasma donations intended for fractionation.

Mapping of the blood activities_2

Blood components processing

- **NCA** is in charge of:
  - ✓ the authorization and the inspection of the blood processing site.
  - ✓ the evaluation, authorization & registration of new Blood Components (BC).

Blood components Storage

- **NCA** is in charge of the authorization and the inspection of the blood storage site in BEs.
- **Regional Health agency (RHA)/Regional Competent Authority (RCA)** is in charge of the authorization and the inspection of the blood storage site in Hospital Blood Banks (HBBs).

Blood components release

- **BEs** are in charge of the designation/nomination of the Responsible release Person
- **NCA** is informed of this designation/nomination and the registration of this Responsible release Person.

Mapping of the blood activities_3

Blood components distribution/issue

- **NCA** is in charge of:
  - ✓ the authorization and the inspection of the blood processing site.
  - ✓ the evaluation, authorization & registration of new Blood Components (BC).

Blood components import

- **NCA** is in charge of the authorization and the inspection of the import blood entities.

Blood components export

- **BEs** are in charge of the BC export.
- **NCA** is informed by BEs of BC exported.

Mapping of the blood activities_4

Blood components human application

- **Regional Health agency (RHA)/Regional Competent Authority (RCA)** is in charge of the registration of facilities (hospitals & clinics) for the medical and diagnostic activities carried out there for the care of patients, including transfusion.
- **NCA** NCA uses RHA/RCA registers for haemovigilance, traceability and collection of transfusion activity denominators.
- **There is no national registry for monitoring the clinical outcomes of routine transfusions** with already authorized BCs. Clinical outcome monitoring of transfused patients is performed for each patient by the medical team

Clinical-outcome registration

- **NCA** is responsible for authorization, registration, supervision of BC clinical trials and clinical-outcome as part of the procedures for evaluating and authorizing new blood components and as part of the comparison of therapeutic strategies.

Mapping of the blood activities_5

Traceability of blood components

- **NCA** is responsible for registration and maintenance of:
  - ✓ the BC coding system
  - ✓ the blood entities/sites coding system
  - ✓ the blood testing coding system (e.g. blood typing coding system …).

Haemovigilance

- **NCA** is responsible for organizing the haemovigilance system & the coordination with other vigilances of health products (MD & IVD vigilances, pharmacovigilance, tissues, cells and organs vigilances). NCA is responsible of the inspection of haemovigilance system in BEs.
- **RHA/RCA** are responsible for implementation at the regional level. **RHA/RCA** are responsible of the inspection of haemovigilance system in HBBs.
- **BEs and facilities** implement haemovigilance, each at their local and regional levels.
- **National Public Health Agency** is responsible for the epidemiological monitoring of blood donors.

Acknowledgements

- Marianne Delville
- Karim Boudjedir
- Sixtine Drougard
- Chloé Freyche

dakujem

grazie

danke

tack

dank u

Thank you for your attention and...

tänan väga

děkuji

blagodaria

благодаря

?

ευχαριστώ

tak

obrigado

dziękuję

köszönöm

paldies

ačiū

aitäh

takk

þakka þér

gracias

niżżik ħajr

хвала

kiitos

mulțumesc

merci