CENTRO NAZIONALE SANGUE

Istituto Superiore di Sanità

The Action Plan of Finland

Anu Puomila

Senior Inspector, Ph.D.

Finnish Medicines Agency

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SoHO field in Finland in 2025

- Finnish Medicines Agency as Competent Authority in blood sector
  - Also in Tissues & Cells, Organs, Medicines, Medical Devices
  - Authorisations, inspections, vigilance, guidance
  - Acting under Ministry of Social Affairs and Health
- Centralised blood system → only one Blood Establishment (Finnish Red Cross Blood Service)
  - Non-profit organisation
  - Based on voluntary unpaid donations
  - 10 fixed blood donation centers, >1000 mobile donation events annually
  - Testing laboratory and processing in one location
  - Finland has not had shortages of blood products during the last decades
  - Not self-sufficient for plasma (for plasma-derived medicinal products)
  - Hospital side of the transfusion chain (blood use) is not currently under Fimea's oversight
- Approximately 50 Tissue Establishments

The Action Plan

- How to prepare for the SoHO Regulation era
  - Competent Authority remains the same
  - Existing already, requiring modifications:
    - Authorising establishments
    - Inspections
    - Vigilance
    - National legislation
  - Need to be established:
    - National emergency plans
    - SoHO preparation authorisation procedure
    - Supply alerts
    - Classification system?

Competent Authority actions

- Finnish Medicines Agency (Fimea) will be the SoHO National Authority (no other SoHO competent authorities nor delegated bodies are foreseen)
  - Fimea SoHO Team has members in SoHO Coordination Board, ECDC National focal points, and European Committee on Blood transfusion (CD-P-TS)
  - Communication with the stakeholders, information sessions etc.
  - Has started an internal project to organise all necessary actions within the SoHO Regulation → 8 work packages
  - Collaborates with Nordic and Baltic colleagues at the Nordic Council of Ministers working group of blood, tissues and cells
    - Small countries
    - Similar views

SoHO establishments

- Current authorisation procedure will be continued to be used
- Only few importing/exporting establishments in Finland
- Amount of new entities/establishments under the SoHO oversight will be expanding
  - Hospital blood banks
  - Hospital pharmacies (which process serum eye drops)
  - Platelet rich plasma in use in many fields
  - Faecal microbiota transfers, human milk banks
  - Testing laboratories, entities applying SoHO etc.

Registers

- EU Platform development by the EC is followed (member in testing group)
- A need to develop also a national SoHO registry is foreseen
  - Registry containing all national SoHO entities, establishments and contact details
  - Risk-based inspection planning
  - Linking vigilance reports, inspection reports, authorisations of establishments and SoHO preparations, activity data
  - Interface between national and EU platform

SoHO preparation authorisations

- Process will need to be developed, no process exists currently
  - Templates, instructions for stakeholders, internal SOPs
- Small country with quite established processes and products → estimated to have low number of high-risk novelties/preparations/changes
- Plan to utilise Fimea's experience of assessing medicinal products and medical devices

Inspections

- All current inspectors are qualified according to SoHO Regulation requirements
- Routine inspections will be continued
  - Mainly on-site inspections, however also remote inspections
- Risk-based inspection planning is foreseen
- Good experiences on Joint inspections with other Member States

Vigilance

- Supervision of vigilance will continue as currently
  - Dedicated vigilance officers handle SARE reports and rapid alerts (they are also inspectors)
  - Approximately 100 reports annually
  - Need to modernise the national process (currently receiving SARE reports via secure email)

Critical SoHOs

- Blood products are seen as critical SoHOs
- The only Blood Establishment will be a critical SoHO entity (also an entity under the NIS2 directive)
- National SoHO emergency plan will be developed
  - At first focus on blood products
- Not yet known how to organise supply alerts for critical SoHO

National legislation

- More stringent measures are not currently foreseen
- Otherwise unpaid donations, except for oocytes, sperm and human milk – upper limits for compensations need to be discussed and set nationally
- Good Practice Guidelines of blood sector have not been translated to national languages (are referred to)
- Several national laws and decrees should be reviewed and updated to comply with the SoHO Regulation

Resources

- Lots of resources need to be dedicated to
  - Participation in working groups (e.g. SCB, EDQM, ECDC, Nordic Council of Ministers)
  - National discussion needs to be organised and led, communication needed
- Need to map
  - Training needs
  - Need for new resources

Thank you!
Kiitos!

anu.puomila@fimea.fi