SoHO Coordination Board (SCB)

Recommendations and Guidance document for the Management of SoHO in Non-Hospital Entities

This Guidance document has been developed by the Registration Wg of the SCB and has been adopted by the SCB as a complementary document to the "Recommendations and Guidance Document for the Management of Substances of Human Origin in Hospitals (ReaderSHip Project)". While the ReaderSHip document focuses specifically on hospital entities, the present Guidance addresses entities and settings involved in the management of substances of human origin that operate outside a hospital setting or a setting of a large entity with various departments.

The objective of this document is to provide additional, targeted guidance for such non-hospital entities, ensuring alignment with the principles, recommendations, and approaches set out in the ReaderSHip document, while considering the specific organisational, operational, and regulatory contexts of these entities.

This Guidance should therefore be read and applied in conjunction with the ReaderSHip document. It is not intended to replace or duplicate the recommendations contained therein, but rather to complement them and support their consistent and coherent implementation across the broader landscape of entities involved in the management of substances of human origin.

Adopted by the SCB on 16 March 2026

Recommendations and Guidance document for the Management of SoHO in Non-Hospital Entities

Including Small or Single-Department Healthcare Facilities

March 2026

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Table of abbreviations

Acronym	Description
CA	Competent Authority
ECDC	European Centre for Disease Prevention and Control
EDQM	European Directorate for the Quality of Medicines and HealthCare
EU	European Union
ICCBBA	International Council for Commonality in Blood Banking Automation
QMS	Quality Management System
SCB	SoHO Coordination Board
SEC	Single European Code
SNA	SoHO National Authority
SoHO	Substances of Human Origin
SOP	Standard Operating Procedure
SPA	SoHO Preparation Authorisation

Glossary

Term	Definition
Adverse Event	Any incident or error associated with SoHO activities that can affect the quality or safety of SoHO in such a way that implies a risk of harm to a living SoHO donor, to a SoHO recipient or offspring from medically assisted reproduction *(Article 3 (44) of the SoHO Regulation).*
Adverse Reaction	Any incident which could be reasonably associated with the quality or safety of SoHO, or their collection from a SoHO donor or human application to a SoHO recipient, that caused harm to a living SoHO donor, to a SoHO recipient or offspring from medically assisted reproduction *(Article 3 (43) of the SoHO Regulation)*.
Clinical-outcome Monitoring Plan	A programme for evaluating the safety and effectiveness of a SoHO preparation following human application *(Article 3 (32) of the SoHO Regulation)*.
Collection	A process by which SoHO are obtained from a person, including any preparatory steps, such as hormone treatment, needed to facilitate the process at, or under the supervision of, a SoHO entity *(Article 3 (22) of the SoHO Regulation)*.
Committee	A subgroup or organisation officially designated to perform a specific function, discussing, or making decisions on particular fields within the hospital. In the context of this document, a committee may include board nurses, physicians, designated delegates, and other relevant personnel. Examples of such committees include the Transfusion Committee and the Transplant Committee, amongst others.
Critical SoHO	A SoHO for which an insufficient supply will result in serious harm or risk of serious harm to recipients' health or in a serious interruption in the manufacture of products regulated by other Union legislation, as referred to in Article 2(6) of the SoHO Regulation, where an insufficient supply of such products will result in serious harm or risk of serious harm to human health *(Article 3 (2) of the SoHO Regulation)*.
End-user	An individual who applies, or under who's responsibility, the SoHO is applied to a recipient.
Grey Literature	Information produced on all levels of government, academia, business and industry in electronic and print formats not controlled by commercial publishing i.e., where publishing is not the primary activity of the producing body.
Haemovigilance	A set of surveillance procedures covering the entire transfusion chain, from the donation and processing of blood and its components, to their provision and transfusion to patients and their followup. Haemovigilance includes the monitoring, reporting, investigation and analysis of adverse events related to the donation, processing and transfusion of blood, as well as the development and implementation of recommendations to prevent their occurrence or recurrence.
Human Application	Being inserted, implanted, injected, infused, transfused, transplanted, ingested, transferred, inseminated or otherwise added to the human body in order to create a biological interaction with that body *(Article 3 (19) of the SoHO Regulation)*.

Physician	In the scope of this document, a person who performs the tasks defined in Article 50 (2) of the SoHO Regulation in the same Member State, and who meets the following minimum requirements: (a) possession of formal qualification as a physician; and (b) at least two years of practical experience in the relevant field.
Personal Data	Any information relating to an identified or identifiable natural person ('data subject'). An identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.
Pseudonymisation	The processing of personal data in such a manner that the personal data can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organisational measures to ensure that the personal data is not attributed to an identified or identifiable natural person.
Quality Manager	The Quality Manager is the person responsible for managing the quality system. Their duties include, but are not limited to, ensuring the implementation of the following: (a) qualification of personnel, (b) verification or validation of processes, (c) qualification, (d) maintenance, (e) cleaning of premises and equipment (f) disinfection and monitoring of premises and equipment, (g) verification or validation of test methods, (h) qualification of materials, (i) qualification and monitoring of suppliers and contractors, (j) document control, (k) retention of records, (l) compliance of all other personnel with requirements, (m) scheduling and follow-up of audits (internal or external ones), (n) follow-up of non-compliances and corrective measures, (o) implementation of risk mapping as part of the quality management system, (p) notably for critical activities.
Quality Management System	A formalised system that documents the process, procedures, and responsibilities to support achieving defined quality standards in a consistent manner (Article 3 (49) of the SoHO Regulation).
Releasing Officer	The person responsible for the release of SoHO within a SoHO establishment who is in the possession of a diploma, certificate or other evidence of formal qualifications in the field of medical, pharmaceutical or life sciences, awarded on completion of a university course of study or a course recognised as equivalent by the Member State concerned, and who has at least two years of experience in the relevant field. (Article 49 of the SoHO Regulation).
Responsible Person	An appointed person in a SoHO entity who has the responsibility of ensuring compliance with the SoHO Regulation (Article 3 (36) of the SoHO Regulation).
Serious Adverse Event	Adverse event that poses a risk of any of the following: a) inappropriate SoHO distribution of, b) a defect posing a risk to SoHO recipients or SoHO donors is detected in one SoHO entity that would have implications for other SoHO recipients or SoHO donors because of shared practices, services, supplies or critical equipment; (c) loss of a quantity of SoHO that causes human applications to be postponed or cancelled; (d) loss of highly matched SoHO or SoHO for autologous use; (e) a mix-up of reproductive SoHO in such a way that an oocyte is fertilised with sperm from a person other than the intended person, or reproductive SoHO are applied to a SoHO recipient other than the intended SoHO recipient; (f) loss of the traceability of SoHO (Article 3 (46) of the SoHO Regulation).

Serious Adverse Reaction	Adverse reaction that results in any of the following: (a) death; (b) life-threatening, disabling or incapacitating condition, including transmission of a pathogen or of a toxic substance that might cause such condition; (c) transmission of a genetic disorder that: (i) in the case of medically assisted reproduction with third-party donation, resulted in pregnancy loss or might result in a life-threatening, disabling or incapacitating condition in the offspring from medically assisted reproduction; or (ii) in the case of medically assisted reproduction in the context of within-relationship use, resulted in pregnancy loss or might result in a life-threatening, disabling or incapacitating condition in the offspring from medically assisted reproduction, due to a pre-implantation genetic test error; (d) hospitalisation or prolongation of hospitalisation; (e) the need for a major clinical intervention to prevent or reduce the effects of any of the results referred to in points (a) to (d); (f) prolonged sub-optimal health of a SoHO donor following single or multiple SoHO donations *(Article 3 (45) of the SoHO Regulation)*.
Single European Code	The unique identifier applied to certain SoHO distributed in the Union *(Article 3 (54) of the SoHO Regulation)*.
SoHO Activity	Those activities that have a direct impact on the quality, safety or effectiveness of SoHO, as follows: (i) SoHO donor registration; (ii) SoHO donor history review and medical examination; (iii) testing of SoHO donors or of persons from whom SoHO are collected for autologous or within-relationship use; (iv) collection; (v) processing; (vi) quality control; (vii) storage; (viii) release; (ix) distribution; (x) import; (xi) export; (xii) human application; (xiii) clinical-outcome registration *(Article 2 of the SoHO Regulation)*.
SoHO Compendium	A list kept up-to-date by the SoHO Coordination Board of decisions, taken at Member State level, and opinions, issued by SoHO Competent Authorities and by the SoHO Coordination Board, on the regulatory status of specific substances, products or activities, and published on the EU SoHO Platform *(Article 3 (41) of the SoHO Regulation)*.
SoHO Competent Authority	An authority designated by the Member State which is conferred with the responsibility for SoHO supervisory activities. The SoHO competent authority or authorities designated shall be independent from any SoHO entity *(Article 5 of the SoHO Regulation)*. SoHO Competent Authorities shall be responsible, within their territory, for SoHO supervisory activities in order to verify the effective compliance by: (a) SoHO entities with the requirements set out in this Regulation; and (b) SoHO preparations with their corresponding authorisation *(Article 8 of the SoHO Regulation)*.
SoHO Coordination Board	A body established to promote coordination between Member States concerning the implementation of the SoHO Regulation (Regulation (EU) 2024/1938) and of the delegated and implementing acts adopted pursuant thereto, and to support them in that coordination, as well as to facilitate cooperation with stakeholders in that regard. It is composed of two permanent members per Member State, nominated based on their role and expertise within their respective SoHO Competent Authorities, along with two alternates. The Board is co-chaired by one representative of the European Commission and one representative of the SoHO national authority of a Member State, elected by and from among its members, with the Commission also providing the secretariat. Observers and experts may be invited to participate in the activities of the SoHO Coordination Board *(Article 68 of the SoHO Regulation)*.

SoHO Donor	A living or deceased SoHO donor. A living SoHO donor refers to living person who has volunteered to a SoHO entity or has been presented by a person granting consent on their behalf, in accordance with national legislation, with a view to making a donation of SoHO, for the purpose of use in a person other than themselves, and other than in situations of within-relationship use. A deceased SoHO donor refers to a deceased person who has been referred to a SoHO entity with a view to SoHO collection, and from whom consent had been granted in that respect or from whom SoHO collection is permitted, in accordance with national legislation *(Article 3 (6) (7) (8) of the SoHO Regulation)*.
SoHO Entity	An entity legally established in the Union that carries out one or more of the SoHO activities: (i) SoHO donor registration; (ii) SoHO donor history review and medical examination; (iii) testing of SoHO donors or of persons from whom SoHO are collected for autologous or within-relationship use; (iv) collection; (v) processing; (vi) quality control; (vii) storage; (viii) release; (ix) distribution; (x) import; (xi) export; (xii) human application; (xiii) clinical outcome registration *(Article 3 (33) of the SoHO Regulation)*.
SoHO Establishment	A SoHO entity that carries out any of the following SoHO activities: both processing and storage, release, import, export *(Article 3 (35) of the SoHO Regulation)*.
SoHO Management	Refers to the oversight, coordination, and implementation of standards and procedures related to any SoHO activities identified in Article 2 of the SoHO Regulation.
SoHO Management Pillars	In this document, SoHO management pillars refer to the key functional areas that structure the recommendations. These pillars include Registration of SoHO Entities (Chapter 2), Vigilance and Reporting (Chapter 3), Activity Data Collection and Reporting (Chapter 4), Traceability (Chapter 5). Throughout the document, references to SoHO Management Pillars will correspond to these defined areas.
SoHO National Authority	An authority designated by the Member State which is conferred with the responsibility for SoHO supervisory activities. While Member States may appoint multiple Competent Authorities, SoHO National Authority serves as the central point of contact, facilitating effective communication and regulatory oversight. In Member States where only one Competent Authority is designated, it is considered the SoHO National Authority by default. The designation of a single SoHO national authority shall not prevent the Member State from assigning certain tasks to other SoHO competent authorities, in particular the management of SoHO rapid alerts *(Article 5 of the SoHO Regulation)*.
SoHO Preparation	A type of SoHO that has been subjected to processing and, where relevant, one or more other SoHO activities referred to in Article 2(1) point (c) of the SoHO Regulation; has a specific clinical indication; and is intended for human application to a SoHO recipient or is intended for distribution *(Article 3 (37) of the SoHO Regulation)*.
SoHO Preparation Authorisation	The formal approval by a SoHO Competent Authority of a SoHO preparation *(Article 3 (38) of the SoHO Regulation)*.
Substance of Human Origin	Any substance collected from the human body, whether it contains cells or not and whether those cells are living or not, including SoHO preparations resulting from the processing of such substance *(Article 3 (1) of the SoHO Regulation)*.

Traceability	The ability to locate and identify SoHO from collection to human application, disposal or distribution for the manufacture of products regulated by other Union legislation, as referred to in Article 2(6) of the SoHO Regulation *(Article 3 (53) of the SoHO Regulation)*.
Vigilance	A set of organised surveillance and reporting procedures relating to adverse reactions and adverse events *(Article 3 (42) of the SoHO Regulation)*.

Table of SoHO activities

SoHO activities that have a direct impact on the quality, safety or effectiveness of SoHO
SoHO donor registration
SoHO donor history review and medical examination
Testing of SoHo donors or of persons from whom SoHO are collected for autologous or within-relationship use
Collection
Processing
Quality control
Storage
Release
Distribution
Import
Export
Human application
Clinical-outcome registration

Checklist – General Recommendations

This checklist provides an overview of checkpoints related to general recommendations for SoHO entities.

Responsible Person (Article 36 SoHO Regulation)

- ❑ Responsible Person appointed
- ❑ Required qualification and experience confirmed
- ❑ Backup person identified for absences
- ❑ Competent Authority informed of any changes

Processes for Registration (Article 35 SoHO Regulation)

- ❑ Key SoHO processes defined and documented
- ❑ Oversight of all SoHO activities ensured (Art 2.1.c SoHO Reg.)
- ❑ Processes proportionate to entity size and activities
- ❑ Quality Management System in place (or established if needed)
- ❑ Core SoHO elements covered (registration, authorisation, traceability, vigilance, reporting)
- ❑ Responsible Person and relevant staff involved

Supporting Documents

- ❑ Relevant guidelines and best practices from CAs / the SoHO Platform identified and used
- ❑ Staff involved in SoHO activities identified and trained
- ❑ Training materials aligned with the Quality Management System
- ❑ Key updates followed (e.g. EU SoHO Platform, Competent Authorities)
- ❑ Supporting documents easily accessible to staff
- ❑ Training activities documented

Communication

- ❑ Responsible Person acts as liaison with Competent Authority
- ❑ Proactive two-way communication established
- ❑ Changes to registered activities or quality systems communicated
- ❑ Safety concerns and regulatory queries raised promptly
- ❑ Communication channels maintained

Checklist for Registration of SoHO Entities 

The recommendations for the registration of SoHO entities are intended to support compliance with the accompanying checklist and, by extension, with the SoHO Regulation.

SoHO Entity Registration

- ❑ **Determine the appropriate registration model:**
  - ❑ Decide whether the SoHO entity will register as:
    - ❑ **A single SoHO entity –** In cases where the enities have an own Quality Management System (**Article 37**) and one designated Responsible Person (**Article 36**) is available for the specific SoHO activities
    - ❑ **A centralised registration for multiple activity addresses or separate entities –** In cases where one unified Quality Management System is covering all included activities and one single Responsible Person for all covered entities
  - ❑ **Ensure the decision reflects:**
    - ❑ Actual SoHO activities conducted
    - ❑ Guidance from the national SoHO Competent Authority
    - ❑ Best practices provided by the SoHO Coordination Board
- ❑ **Compile all administrative information required (Article 35)**
- ❑ **Conduct a self-assessment for "Critical SoHO Entity" status**
  - ❑ Identify whether the entity performs activities involving SoHO listed as critical by the Member State on the EU SoHO Platform.
  - ❑ Follow the standardised methodology for criticality assessment established by the SoHO Coordination Board.
  - ❑ If classified as a critical SoHO entity, submit all additional data required on the EU SoHO Platform or national registers
- ❑ **Identify existing tools and systems that support registration**
- ❑ **Complete the Registration Process:**
  - ❑ Identify which registration system applies (in line with **Article 16** and with national processes):
    - ❑ EU SoHO Platform
    - ❑ National registry
- ❑ **Notify SoHO Competent Authorities of significant changes, including:**
  - ❑ Organisational restructuring
  - ❑ Cessation or addition of activities
  - ❑ Submit updates via the EU SoHO Platform or national register, as applicable
  - ❑ Follow national guidance for change notifications

SoHO Preparation Authorisation

If the entity performs **bedside preparations**, a **SoHO Preparation Authorisation may be required**. When using preparations from other SoHO establishments, the entity must cooperate by providing risk-assessment data, relevant clinical or scientific information, and clinical outcome data (where applicable). ■

Checklist for Vigilance and Reporting

The recommendations for vigilance and reporting are intended to support compliance with the accompanying checklist and, by extension, with the SoHO Regulation.

- ❑ **Maintain a system** for detecting, investigating and recording information concerning Adverse Reactions and Adverse Events, including those detected during clinical-outcome monitoring as part of a SoHO Preparation Authorisation application, as per **Article 44(1)**.
- ❑ In case of **emergence of concerning serious genetic conditions** in children born from third-party donation (**Article 44(2)**):
  - ❑ **Encourage prospective parents** to promptly inform the SoHO entity where they were treated, in alignment with applicable national legislation;
  - ❑ **Inform the SoHO establishment without undue delay** that released the reproductive SoHO for human application, so that the SoHO establishment can investigate **the suspected Serious Adverse Reaction and Event** and prevent further distribution of SoHO from the implicated SoHO donor.

Notification responsibilities vary depending on the type of SoHO entity and its relationship with a SoHO establishment:

SoHO entities operating under an agreement with a SoHO establishment or receiving SoHO from such establishments shall:

- ❑ Communicate without undue delay any Adverse Reactions or Events to the SoHO establishment for which they perform SoHO activities or to the SoHO establishment that distributed the SoHO to them. In these cases, the SoHO establishment is responsible for investigating and reporting to the SoHO Competent Authority (**Article 44(4)**).

SoHO entities not operating under an agreement with a SoHO establishment or receiving SoHO from one shall:

- ❑ Submit a notification to the SoHO Competent Authority without undue delay in case they detect or suspect that an Adverse Reaction or Event falls within the definition of a Serious Adverse Reaction or Serious Adverse Event as defined in the SoHO Regulation. The required content for the notification is detailed in **Article 44(3)**.
- ❑ Investigate and report Serious Adverse Reactions or Events directly to the SoHO Competent Authority (as per **Article 44(4)**).

- ❑ If the SoHO entity receives information regarding a serious incident and associated safety corrective and preventive actions related to a medical device or in vitro diagnostic medical device used by a SoHO entity, this information must be **communicated to the SoHO Competent Authority,** as per **Article 44(5)**).
- ❑ **Establish a procedure** to withdraw from distribution or use any SoHO affected (or suspected to be affected) by Serious Adverse Reactions and/or Events. Procedures involving reproductive SoHO must align with national legislation (**Article 44(6)**).
- ❑ Conduct an **investigation** of each Serious Adverse Reaction and/or Event detected by or communicated to the SoHO entity.
  - ❑ **Provide an investigation report** of the Serious Adverse Reaction and/or Event to the SoHO Competent Authorities with the information indicated in **Article 44(7)**.▶

- **Communicate** the necessary information to facilitate traceability and ensure quality and safety concerning a Serious Adverse Reaction or Event to (**Article 44(8)**):
  - Other SoHO entities engaged in the collection, processing, testing, storage and distribution of SoHO collected from the same SoHO donor, or otherwise possibly affected.
  - **The organ procurement organisation,** in cases where the implicated SoHO donor has also donated organs;
  - **Manufacturers,** in cases where SoHO collected from that SoHO donor have been distributed for the manufacture of products regulated by other Union legislation.■

Checklist for Activity Data Collection and Reporting

The recommendations for Activity data collection and reporting are intended to facilitate compliance with the corresponding checklist and, consequently, with the requirements of the SoHO Regulation. The checklist outlines the key steps necessary to collect and report data from the various SoHO activities performed within the SoHO entity, in accordance with the SoHO Regulation.

- ❑ **Identify the SoHO activities conducted** within the SoHO entity from which data must be collected and reported (see **Article 41(1)** of the SoHO Regulation).
- ❑ **Review the most up-to-date list of required datasets**, which are published by the European Commission and available in the EU SoHO Platform.
- ❑ **Collect the required dataset** for each of the SoHO activities identified.
- ❑ **Submit an annual report** of the data collected by a deadline indicated by your Competent Authority of the subsequent year via the tool indicated by the Member State, which may be the **EU SoHO Platform** (see **Article 41(4)**) or a **designated national or international registry** (see **Articles 41(5) and 31(2)**).■

Checklist for Traceability

The recommendations for Traceability are designed to support compliance with the accompanying checklist and, by extension, with the SoHO Regulation. The checklist sets out the key steps that a SoHO entity should consider when implementing a traceability system in accordance with the SoHO Regulation.

- ❑ **Implement appropriate procedures to ensure traceability and coding of SoHO** (traceability system).
  - ❑ The traceability system shall link each SoHO donor (or the person from whom SoHO are collected) to their corresponding SoHO and to all documents, samples SoHO preparations and SoHO entities associated with the SoHO.
  - ❑ The traceability data shall be appropriately safeguarded.
  - ❑ In case of SoHO entity ceases its activity, the Competent Authority shall be notified and all traceability data shall be transferred to designated SoHO entity according to corresponding contractual agreement.
- ❑ **Implement appropriate procedures to ensure accurate coding of SoHO.**
  - ❑ Ensure correct application of code onto the SoHO or under certain circumstances on accompanying documents.
- ❑ **Implement a labelling system** that complies with the requirements outlined in the relevant technical guidelines ■

1. Background

The European Union has long maintained a robust legal framework for the quality and safety of Substances of Human Origin (SoHO), including blood, tissues, and cells. These standards were originally laid down through the EU Blood Directive (2002/98/EC) and the EU Tissues and Cells Directive (2004/23/EC). However, over the past two decades, **developments in healthcare**, **biotechnology**, and **public health** policy have **significantly evolved**, exposing **gaps in the applicability of existing legislation** to emerging practices and technologies.

To address these challenges, in July 2024 the Council of the **European Union adopted a new, unified legal framework: Regulation (EU) 2024/1938 on quality and safety standards for SoHO intended for human application** (hereinafter referred to as the **SoHO Regulation**), which was approved by the European Parliament. This Regulation replaces the previous directives and will become **applicable in 2027**[1]. It **extends** the **scope of EU legislation** to include additional SoHO types (such as human **breast milk** and **intestinal microbiota**) and introduces stricter quality and traceability rules, improved digital infrastructure, and a harmonised system for registration, authorisation, and oversight across all Member States.

Importantly, the SoHO Regulation introduces **new requirements for SoHO management in SoHO entities and SoHO Competent Authorities** which will affect the daily activities of actors involved in SoHO management, **including non-hospital entities** such as **SoHO registries**, **private laboratories**, **clinics** or **private practices (e.g. dental clinics or fertility centers),** among others.

As a result, these actors will need to **implement new or adapt their current coordination models for administrative and legal support**, as well as revise their internal processes to ensure the structured and **compliant implementation of the SoHO Regulation's quality management system** requirements across those entities, in alignment with EU-wide standards and operational best practices. In recognition of the significance of the SoHO Regulation within the evolving SoHO landscape, the European Commission has already implemented, and will continue to propose, a range of measures to support stakeholders across Member States in the coming years, in accordance with Chapter X (**Articles 70-72**) of the SoHO Regulation.■

[1]Some parts will become applicable in 2028. For more details see Chapter XIII of the SoHO Regulation

2. Purpose of the document

If you consider that your entity is more appropriately situated within a hospital context or is involved in a larger setting comparable to a hospital, with extensive structures and broad expertise across various SoHO-relevant areas as well as related management divisions, the "Recommendations and Guidance document for the Management of Substances of Human Origin in Hospital Entities" may be the most appropriate reference.

The "**Recommendations and Guidance document for the Management of Substances of Human Origin in Non-hospital Entities**" is a practical tool designed to **support professionals involved in the use of SoHO in their daily activities** in **non-hospital entities**, or entities that are not part of a large hospital setting, such as **private laboratories**, **clinics**, **SoHO registries**, or **private practices**, **among others**. It provides legal and administrative guidance to enhance quality and safety in SoHO management and to ensure compliance with the SoHO Regulation.

SoHO entities performing any of the **SoHO activities listed in Article 2 (1) c) of the SoHO Regulation** need to register their SoHO-related activities using either the registration form on the EU-SoHO platform or any national registration system, as laid down in **Article 16 (1) and (2)** of the SoHO Regulation. Therefore, the following SoHO activities according to **Article 2 (1) c)** of the SoHO Regulation need to be considered:

- SoHO donor registration[2]
- SoHO donor history review and medical examination
- Testing of SoHO donors or of persons from whom SoHO are collected for autologous or within-relationship use
- Collection
- Processing
- Quality control
- Storage
- Release
- Distribution
- Import
- Export
- Human application
- Clinical-outcome registration ▶

[2]Entities that register prospective living SoHO donors, recording the information needed to identify a match with prospective SoHO recipients in the same Member State or internationally, should be considered as SoHO entities. The registering of persons that indicate their consent to donate tissues after death, or from whom donation is permitted in accordance with national legislation, should not be considered as SoHO donor registration within the meaning of this Regulation and should not, therefore, require the entity carrying out that activity to register as a SoHO entity (see Recital 11 of Regulation (EU) 2024/1938).

2. Purpose of the document

The obligation to register as a SoHO entity applies to any organisation that performs one or more of the SoHO activities listed in Article 2(1)(c) of Regulation (EU) 2024/1938. This requirement applies regardless of whether the substances are intended for autologous use, allogeneic use, or use within a relationship.

As illustrated by the list above, the SoHO activities defined in the SoHO Regulation cover all steps from SoHO donor registration to human application and clinical outcome registration. SoHO can also be used to manufacture products regulated by other Union legislation, namely medical devices, regulated by Regulation (EU) 2017/745 of the European Parliament and of the Council, medicinal products, regulated by Directive 2001/83/EC of the European Parliament and of the Council, advanced therapy medicinal products, regulated by Regulation (EC) No 1394/2007 of the European Parliament and of the Council, and investigational medicinal products, regulated by Regulation (EU) No 536/2014 of the European Parliament and of the Council. This Regulation should apply without prejudice to Union legislation on genetically modified organisms. In this context as well, registration of specific activities is generally required[3].

This document will give guidance on registration of SoHO entities performing any of the listed SoHO activities. It includes recommendations for different relevant fields, such as:

- General recommendations;
- SoHO management registration activities (see Article 16 and 35, SoHO Regulation);
- Vigilance and Reporting (see Article 44, SoHO Regulation);
- Activity Data Collection and Reporting (see Article 41, SoHO Regulation);
- Traceability (see Article 42, SoHO Regulation).

This guide also includes an example on SoHO preparation authorisation (SPA) procedures (see *Recommendation 5*), although not all of the addressed facilities may require a SoHO preparation authorization (see Article 39, SoHO Regulation).

This guide, therefore, has been developed to provide practical recommendations and legal-administrative guidance to support non-hospital entities in navigating the new regulatory environment. It highlights the obligations and opportunities introduced by the SoHO Regulation and outlines concrete steps towards a compliant, safe and efficient SoHO management system. Finally, the implementation of the recommendations calls for enhanced coordination between SoHO entities, SoHO establishments, and other relevant stakeholders, to ensure that the entire SoHO management value chain meets the highest standards of quality and safety.■

[3]For further information, see Recital 32 and Article 2(6) and Article 2(7) of Regulation (EU) 2024/1938 (SoHO Regulation).

3. Roadmap for SoHO entities

Under the SoHO Regulation (see **Article 35**), all SoHO entities are required to register using the EU SoHO Platform or a national register (see **Article 16**). To support an effective registration process, a structured set of steps is proposed for entities to follow. Following a thorough review of the SoHO Regulation and the present document, an entity should undertake several key steps.These steps include identifying all SoHO-related activities conducted, familiarisation with the registration process, designating of a potential Responsible Person, Quality Management System, evaluating the applicable registration mechanisms for entities; and compiling all necessary information to ensure accurate and complete registration. Figure 1. presents a roadmap to ensure legal compliance, facilitate internal organisation, and support smooth registration to either the EU SoHO Platform or the national registration system, as specified by the Member State: ▶

- **Familiarise Yourself with the Legal Framework**
  Review the SoHO Regulation and accompanying Commission materials (see EU SoHO Platform).
- **Identify whether you perform SoHO activities**
  Determine whether your organisation performs one or more SoHO activities as defined in Article 2 (1) (c) of the SoHO Regulation.
- **Familiarise yourself with the Registration Process**
  Identify whether registration must be completed through the EU SoHO Platform or a national system depending on your Member State's implementation, in accordance with Article 16 of the SoHO Regulation.
  see Chapter 2, Recommendation 5, Recommendation 6
- **Appoint the Responsible Person**
  Designate a Responsible Person in accordance with Article 36 of the SoHO Regulation.
  see Chapter 1, Recommendation 1
- **Assess Existing Quality Management Systems (QMS)**
  Review whether a QMS already exists and whether it can serve as a foundation for alignment with the Regulation's requirements (see Article 37 of the SoHO Regulation).
  see Chapter 1, Recommendation 2

- **Designate QMS Maintenance Roles**
  Verify whether individuals are already assigned to maintain the QMS. If not, establish responsible roles in line with Article 37 of the SoHO Regulation.
  see Chapter 1, Recommendation 2, Recommendation 3
- **Adapt the QMS to SoHO Requirements**
  A new or existing QMS must be maintained and updated according to Article 37 of the SoHO Regulation.
  see Chapter 1, Recommendation 2, Recommendation 3
- **Check National Notification Requirements**
  Familiarise yourself with national procedures regarding the notification of the Responsible Person and take any required administrative steps.
- **Summarise Registration Requirements**
  Consolidate all prerequisites needed to complete registration, as outlined in Article 35 of the Regulation. --
  see Chapter 2, Recommendation 5, Recommendation 6
- **Register Your Entity**
  Complete the registration either via the EU SoHO Platform or your national system, depending on your Member State's implementation (Article 16).
  see Chapter 2, Recommendation 5, Recommendation 6

Figure 1. Roadmap for the registration of a SoHO entity

3. Roadmap for SoHO entities

Once these steps are completed, your facility is registered as a SoHO entity can carry out the activities for which it has been registered or for which it has been authorised under the new SoHO regulation.

Note that, depending on the SoHO acitivities your SoHO entity is carrying out, there **may be a need for the entity to be authorized as a SoHO establishment**, see **Article 35** of SoHO Regulation in conjunction with **Articles 45 to 51** of the SoHO Regulation.

These recommendations are designed to assist you at each phase of the procedure. It is recommended that you commence with an examination of Chapter 1, which delineates the overarching recommendations. This chapter delivers a foundational comprehension of the requisite actions to be undertaken. Chapter 2 delivers instruction on the registration of the entity. Subsequently, Chapters 3 to 5 offer more **detailed information** of the steps outlined in Chapter 1, serving to facilitate the set-up of your entity.■

4. Overview of Recommendations

The preceding Roadmap for SoHO entities outlines the main steps that an entity may undertake to achieve proper registration as a SoHO entity.

Following registration, the SoHO entity may commence or continue carrying out the activities for which it has been registered. To conduct these SoHO activities, a set of recommendations has been proposed to facilitate compliance with the new SoHO Regulation, while simplifying processes and reducing administrative burden for SoHO entities and professionals.

An overview of these recommendations is presented below (Figure 2).■

General Recommendations

- **R1** Designate a Responsible Person and (an) alternate(s).
- **R2** Implement standardised processes for SoHO management oversight.
- **R3** Gather and use supporting documents to integrate best practices for SoHO management.
- **R4** Communicate with SoHO Competent Authorities to ensure alignment with the SoHO Regulation and guarantee effective SoHO management.

Recommendations applicable to specific SoHO management activities

SoHO Entity Registration

- **R5** Implement a standardised process for the collection of administrative information for SoHO entity registration.
- **R6** Involve relevant personnel in the oversight of the SoHO entity registration process.

Vigilance and reporting

- **R7** Implement a standardised process for Vigilance and Reporting.
- **R8** Ensure proper monitoring and reporting of Adverse Reactions and Adverse Events.
- **R9** Ensure pseudonymisation when sharing data.
- **R10** Involve relevant personnel in the oversight of vigilance and reporting.
- **R11** Gather and use supporting documents to integrate best practices and ensure team's capacities for vigilance and reporting protocols.

Activity data collection and reporting

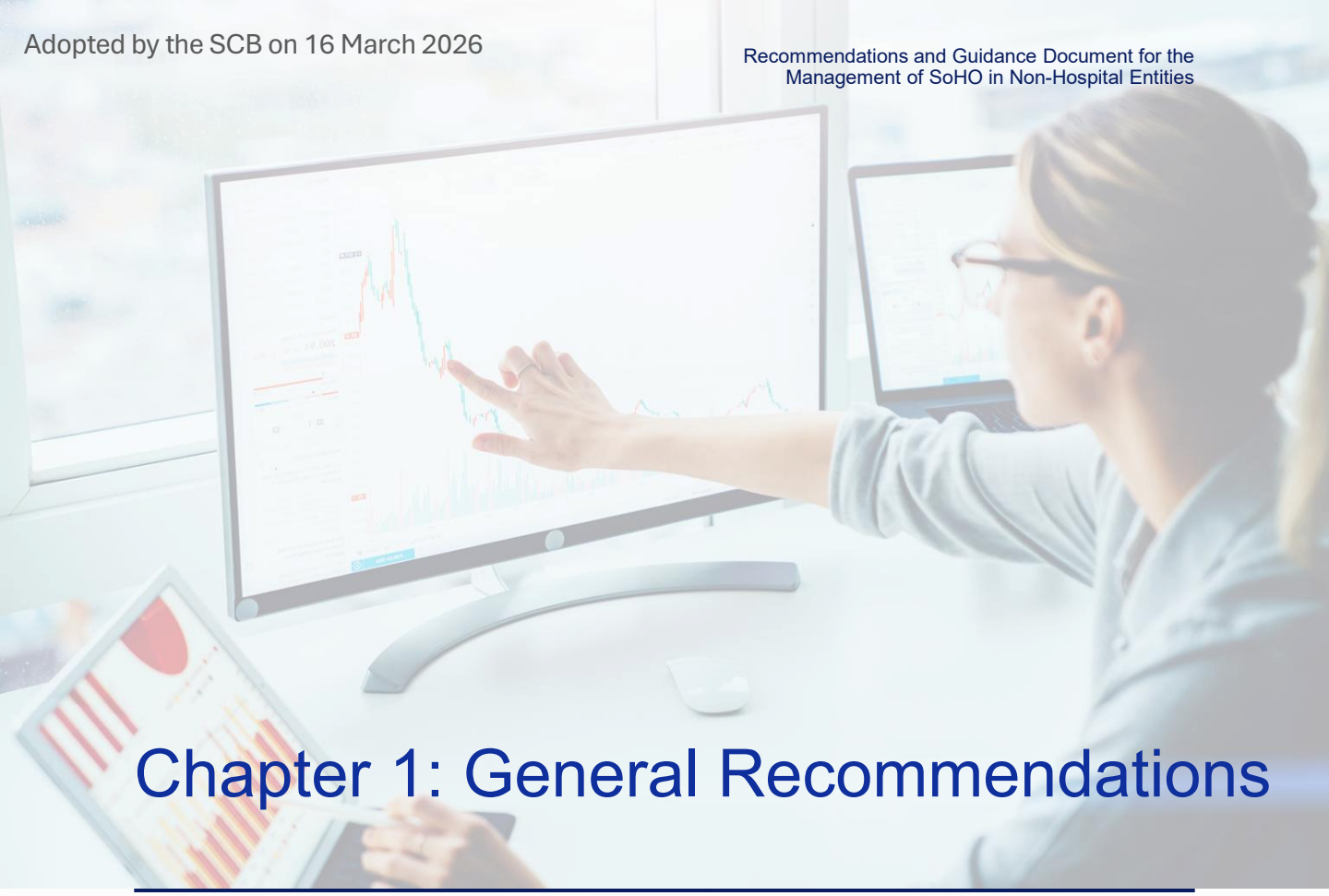
- **R12** Implement a standardised process for SoHO activity data collection and reporting
- **R13** Involve relevant personnel in the oversight of SoHO activity data collection and reporting.
- **R14** Gather and use supporting documents to integrate best practices and ensure team's capacities for internal SoHO activity data collection and reporting protocols

Traceability

- **R15** Get familiar with a Traceability system.
- **R16** Apply the Single European Code.
- **R17** Implement a labelling system.
- **R18** Implement standardised processes to ensure traceability.
- **R19** Involve relevant personnel in the oversight of traceability (if applicable).
- **R20** Gather and use supporting documents to integrate best practices and ensure team's capacities for traceability protocols.

Figure 2 Overview of the Recommendations

5. Recommendations



Chapter 1: General Recommendations

The preceding Roadmap for SoHO entities outlines the main steps that an entity may undertake to achieve proper registration as a SoHO entity.

This chapter will give you general insight of the steps to undertake before starting as a SoHO-entity.

Recommendation 1. Designate a Responsible Person and (an) alternate(s).

Recommendation 2. Implement standardised processes for SoHO management oversight.

Recommendation 3. Gather and use supporting documents to integrate best practices for SoHO management.

Recommendation 4. Communicate with SoHO Competent Authorities to ensure alignment with the SoHO Regulation and guarantee effective SoHO management.

Recommendation 1

Designate a Responsible Person

In accordance with **Article 36** of the **SoHO Regulation, SoHO entities must designate a Responsible Person to ensure that all SoHO activities carried out within the entity comply with the requirements of the SoHO Regulation.** While the Responsible Person must be actively engaged in and aware of all ongoing SoHO activities, they are not necessarily required to perform these activities personally (see Recommendation 2 for further details).

The designated Responsible Person must **meet the following criteria**, as stipulated in **Article 36**:

- Be in possession of a diploma, certificate, or other formal qualification in medical, pharmaceutical, or life sciences, awarded upon completion of a university course or recognised as equivalent by the Member State.
- Shall have at least two years of professional experience in the relevant field.

When designating the Responsible Person, SoHO entities are encouraged to **leverage existing roles** if available, such as **laboratory directors, laboratory personnel, medical directors, physicians** where appropriate. To properly identify existing roles, an organisational chart can be drafted which shows the deployment of SoHO activities and all the units and professionals involved.

To ensure continuity, alternate professionals capable of assuming the responsibilities of the Responsible Person during absences (e.g. annual leave, sick leave or working shifts) should be identified. Any alternate professional which may replace the Responsible Person permanently or temporarily must also meet the qualification criteria set out above at the time taking over the responsibility of the previous Responsible Person. In the event of a replacement, the SoHO entity must inform their SoHO Competent Authority without undue delay of the name and contact details of the new Responsible Person and the date on which the responsibility of that person is assumed.■

Checklist

- *Responsible Person appointed (Article 36, SoHO Regulation)*
- *Required qualification and experience confirmed*
- *Backup person identified for absences*
- *Competent Authority informed of any changes*

Additional specific actions for a Responsible person are detailed in the corresponding recommendations:

- Recommendation 6: Involve relevant personnel in the oversight of the SoHO entity registration process
- Recommendation 10: Involve relevant personnel in the oversight of vigilance and reporting
- Recommendation 13: Involve relevant personnel in the oversight of SoHO activity data collection and reporting
- Recommendation 19: Involve relevant personnel in the oversight of traceability, if applicable

Recommendation 2

Implement standardised processes for SoHO management oversight

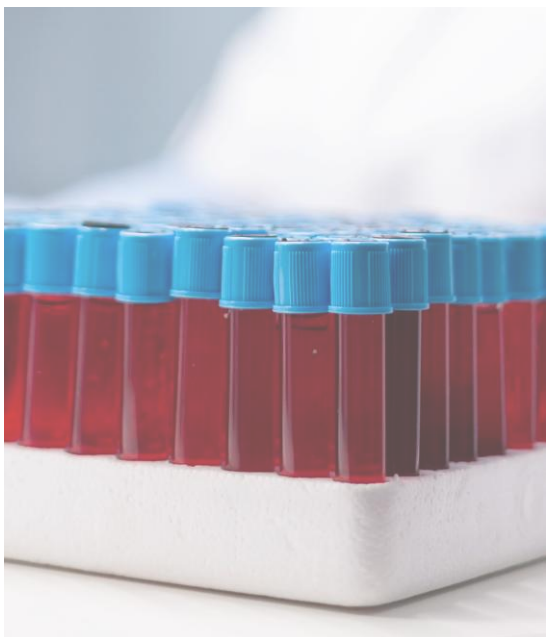
Implementing standardised processes can facilitate the effective implementation of the SoHO Regulation across the various SoHO management pillars, namely: **SoHO entity registration,**, **vigilance and reporting, activity data collection and reporting**, **traceability**.

Standardised processes support the identification of the information, data, and actions required for **effective oversight**, while also providing **clear guidance** to ensure compliance with the SoHO Regulation.

The **definition and implementation of these standardised processes** should be proportionate to the size of the SoHO entity and scope and complexity of the SoHO activities performed. Aligning processes with the specific operational needs of the entity will facilitate oversight and enhance implementation feasibility.

To begin developing these processes, SoHO entities should **consider the following criteria**:

- **All SoHO activities conducted within the SoHO entity** should be taken into account.
- **Information contained in the already existing Quality Management System** may be consulted and used to inform the process design.
- **If necessary, a new Quality Management System must be established**. A quality management system is a formalised system that documents the process, procedures, and responsibilities to support achieving defined quality standards in a consistent manner (**Article 3.49** of the SoHO Regulation).
- All processes should be **aligned with the Quality Management System** of the SoHO entity;
- The processes should encompass, at least, the following SoHO management pillars:
  - SoHO Entity Registration
  - SoHO Preparation Authorisation (if applicable)
  - Vigilance and Reporting
  - Activity Data Collection and Reporting (if applicable)
  - Traceability
- Further general topics that must be covered by the Quality Management System: standard operations procedures describing the relevant processes concerning SoHO (transport, storage, application, disposal etc.), training manuals, self inspection and corresponding records ▶



To support the development and implementation of these processes, SoHO entities may consider the following actions:

1. **Engage relevant personnel** within the SoHO entity to coordinate, develop, and disseminate standardised processes. These may include:
   - The Responsible Person
   - Professionals supporting the Responsible Person
   - Other personnel involved in or working with the Quality Management System (e.g., Quality Managers)

2. **Use existing information and documentation** related to SoHO management activities, SoHO personnel and available guidelines to:
   1. Identify which activities within the SoHO entity require formalised processes.
   2. Gather documents, guidelines, or data useful for defining standardised processes. Guidelines from the following sources may be considered:
      - SoHO Competent Authorities
      - European Centre for Disease Prevention and Control (ECDC)
      - European Directorate for the Quality of Medicines and HealthCare (EDQM)
      - World Health Organisation (WHO)
      - Guidelines and other relevant documents made available on the SoHO Platform by the European Commission

   3. **Define the processes to be implemented.** ■

Checklist

- *Key SoHO processes defined and documented*
- *Oversight of all SoHO activities ensured*
- *Processes proportionate to entity size and activities*
- *Quality Management System in place (or established if needed)*
- *Core SoHO elements covered (registration, authorisation, traceability, vigilance, reporting)*
- *Responsible Person and relevant staff involved*

Additional specific actions for each SoHO management activities are detailed in the corresponding recommendations:

- Recommendation 5: Implement a standardised process for the collection of administrative information for SoHO entity registration
- Recommendation 7: Implement a standardised process for Vigilance and Reporting
- Recommendation 12: Implement a standardised process for SoHO activity data collection and reporting
- Recommendation 18: Implement standardised processes to ensure traceability

Recommendation 3

Gather and use supporting documents to integrate best practices for SoHO management

Collecting and using relevant **supporting documents, and integrating best practices**, will help ensure that all professionals involved in SoHO management are adequately trained and able to carry out their responsibilities effectively.

Supporting documentation may include existing materials and guidelines issued by organisations that promote quality, safety, and efficiency in the field. Examples include:

- **Technical guidelines** published by the ECDC **and the** EDQM, which will be made available via the EU SoHO Platform
- **Best practices** developed by the **SoHO Coordination Board** and available via the EU SoHO Platform.
- National guidelines and best practices provided by the SoHO Competent Authorities

The Responsible Person must ensure that all professionals involved in SoHO management receive adequate training to carry out SoHO activities, in accordance with regulatory requirements, ensuring the highest standards of quality and safety.

To support this objective, SoHO entities may **designate relevant personnel to assist the Responsible Person** with the implementation of this recommendation. The following actions are suggested:

1. **Identify the professionals** who require training.
2. **Communicate and coordinate with the Releasing Officer** (as in **Article 49**) **and/or the Physician** (as defined in **Article 50**) **of the collaborating SoHO establishment that receives the collected SoHO or provides the applied SoHO preparations to exchange relevant information and supporting documents.** The SoHO establishment could furthermore provide training for the relevant personnel.
3. **Ensure that the most recent guidelines, templates, and best practices** from external sources **are incorporated** into the SoHO entity's training materials and in the Quality Management System.
    - Staying updated with the latest guidelines can be challenging. To overcome this, entities may subscribe to regular updates from the ECDC, EDQM, and other relevant European Commission bodies, and seek support from SoHO Competent Authorities or neighboring SoHO entities could also be considered.
4. **Ensure that all available resources are easily accessible** to the identified staff.
5. **Use internal communication channels such as emails, newsletters, or Bulletin systems** to share updates and encourage staff to review new or revised documents. ▶

6. **Record the implemented training and development** measures in compliance with the quality management system

The use of supporting documentation and the integration of best practices is recommended throughout the entire end-to-end SoHO management process. It is particularly beneficial for the following SoHO management activities:

- SoHO Preparation Authorisation (if applicable)
- Vigilance and Reporting
- Activity Data Collection and Reporting (if applicable)
- Traceability ■

Checklist

- *Relevant guidelines and best practices from CAs/ the SoHO Platofrm identified and used*
- *Staff involved in SoHO activities identified and trained*
- *Training materials aligned with the Quality Management System*
- *Key updates followed (e.g. EU SoHO Platform, Competent Authorities)*
- *Supporting documents easily accessible to staff*
- *Training activities documented*

Further details on training-related considerations for each SoHO management activity can be found in the corresponding recommendations:

- Recommendation 11: Gather and use supporting documents to integrate best practices and ensure team's capacities for vigilance and reporting protocols
- Recommendation 14: Gather and use supporting documents to integrate best practices and ensure team's capacities for internal SoHO activity data collection and reporting protocols
- Recommendation 20: Gather and use supporting documents to integrate best practices and ensure team's capacities for traceability protocols

Recommendation 4

Communicate with SoHO Competent Authorities to ensure alignment with the SoHO Regulation and guarantee effective SoHO management

Effective **communication between SoHO entities and SoHO Competent Authorities or delegated bodies** pursuant to Article 9 of the SoHO Regulation is essential to ensure alignment with the SoHO Regulation and to facilitate proper oversight of SoHO management. Communication may be initiated by the SoHO Competent Authority or the delegated body; however, SoHO entities should adopt a proactive approach in fostering and maintaining a two-way dialogue.

The following scenarios particularly warrant bidirectional communication:

- Implementation of changes to registered SoHO activities that may require prior authorisation.
- Clarification of regulatory grey areas or queries arising from cross-border collaboration projects involving SoHO.
- Addressing safety concerns.
- Seeking guidance on regulatory requirements for new products.
- Resolving issues related to registration, biovigilance, or clinical-research questions, among others.

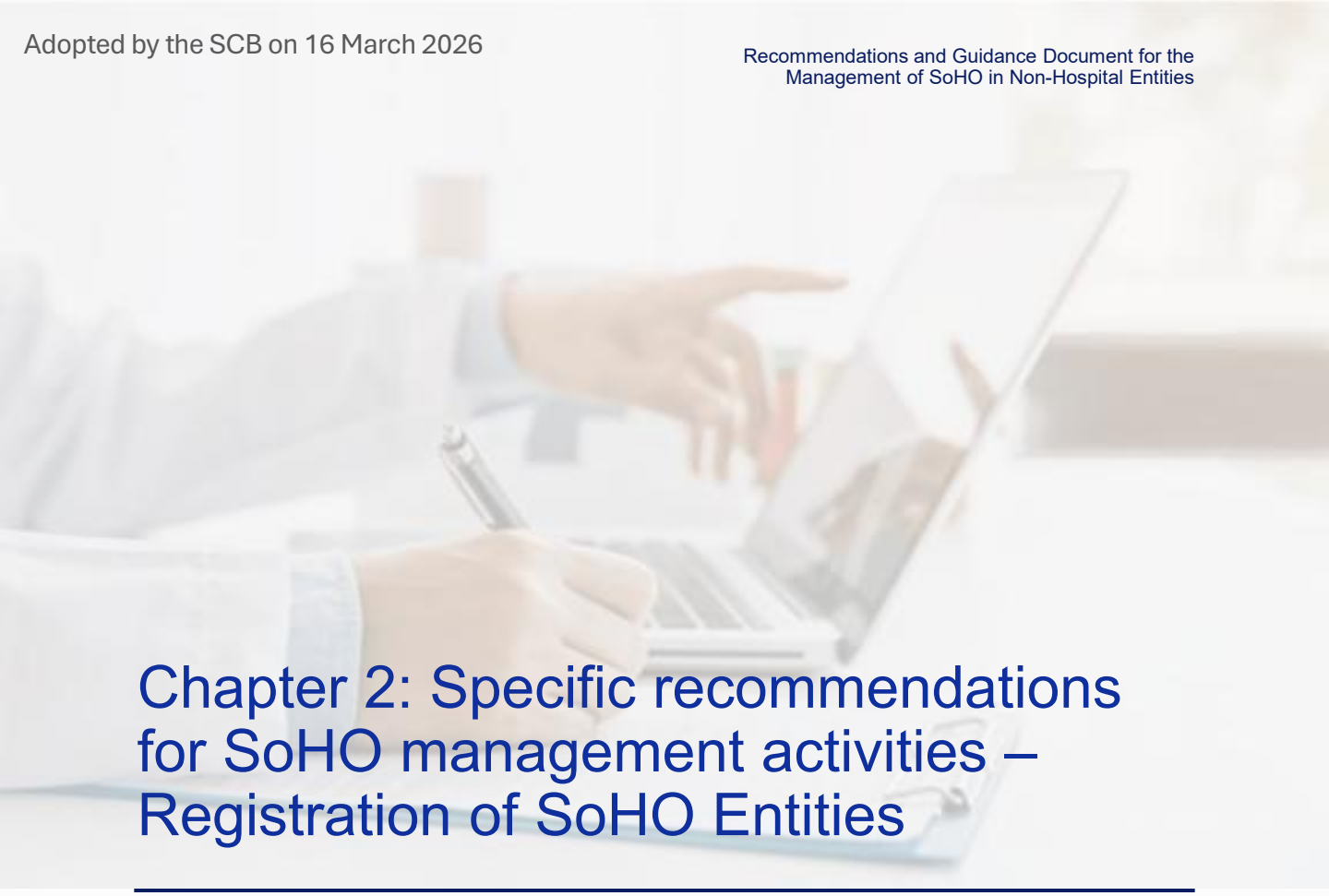
The **Responsible Person** should act as the **designated liaison for communication with the SoHO Competent Authority**, facilitating clarity, consistency and accountability.

To strengthen communication, the following actions are recommended:

1. **Establish and maintain communication channels** (e.g., email correspondence, formal meetings, or other communication tools), as agreed with or provided by the SoHO Competent Authority or the delegated body. These channels should be used to raise questions, seek clarifications, and remain informed about regulatory updates and expectations, among others.
2. **Attend to the workshops or training sessions when organised by SoHO Competent Authorities** to remain up to date with evolving regulatory requirements, technical standards, and best practices.■

Checklist

- *Responsible Person acts as liaison with Competent Authority*
- *Proactive two-way communication established*
- *Changes to registered activities or quality systems communicated*
- *Safety concerns and regulatory queries raised promptly*
- *Communication channels maintained*



Chapter 2: Specific recommendations for SoHO management activities – Registration of SoHO Entities

According to the SoHO Regulation, any entity intending to carry out SoHO activities must be registered as a SoHO entity via the EU SoHO Platform or through a tool indicated by the SoHO Competent Authority in the SoHO entity's Member State. The objective of this registration is to ensure that all SoHO activities undertaken in SoHO entities are known to the national or local authorities. Furthermore, SoHO entities are required to promptly report any significant updates regarding their activities, processes, and status (e.g., changes or cessation of activities) via the EU SoHO Platform or the tool designated by the SoHO Competent Authority in the SoHO entity's Member State.

Recommendation 5. Implement a standardised process for the collection of administrative information for SoHO entity registration.

Recommendation 6. Involve relevant personnel in the oversight of the SoHO entity registration process.

Recommendation 5

Implement a standardised process for the collection of administrative information for SoHO entity registration

Following a **standardised process** can support compliance with the SoHO Regulation in relation to Registration, by helping to **identify the information, data, and activities** required to meet the requirements set out in **Article 35.**

To properly go through the registration process, SoHO entities may consider the following actions:

1. **Decide on the appropriate registration model**. SoHO entities may choose between:
   - **Registering as a single SoHO entity**, which must have its own Quality Management System (**Article 37**) and Responsible Person (**Article 36**).
   - **Centralising the registration for more activity addresses or multiple separate entities under one SoHO entity is only possible if all of them are part of the same legal entity.** In such cases, a single Quality Management System (article 37) must be implemented, and one single Responsible Person must be designated (article 36).

   This decision should reflect the specific SoHO activities carried out within the SoHO entity and be aligned with the strategic guidance of the National SoHO Competent Authority. Competent Authorities and best practices developed by the SoHO Coordination Board may support SoHO entities in the registration process.

   SoHO entities may request an opinion from a SoHO Competent Authority or delegated body in their territory as to whether the activities they carry out are subject to the registration requirements or if additional authorisation requirements of the SoHO Regulation would apply.

2. **Identify all administrative information required for SoHO entity registration,** as outlined in **Article 35** of the SoHO Regulation. This includes all necessary data to ensure regulatory compliance and proper registration of the SoHO entity.
   - SoHO entities shall carry out a **self-assessment** to determine whether they **qualify as a critical SoHO entity**. In conducting this assessment:
   - The SoHO entity is required to adhere to a standardised approach, as devised by the SoHO Coordination Board, for the evaluation of criteria regarding critical SoHO entities. This obligation arises when the SoHO entity engages in activities involving SoHO that are included in its Member State's list of critical SoHO on the EU SOHO platform.
   - In cases where the SoHO entity engages in activities involving critical SoHO, as specified on the Member State's list of critical SoHO available on the EU SoHO platform, it is obligatory for the entity to undertake a self-assessment concerning its criticality. This self-assessment is incorporated within the registration module on the EU SoHO platform. In all other circumstances, the self-assessment must be submitted through the national registration process, utilising the national register.
   - If the self-assessment indicates that the SoHO entity may meet the criteria of a critical SOHO entity, this information should be reported through the EU SOHO platform or via the national registers to the SoHO Competent Authority, which will then assess and confirm or reject its critical status.
   - If the entity is defined as a **critical SoHO entity,** all additional information as indicated in the EU-SoHO-Platform or national regiries required for registration must also be collected and submitted. ▶

3. **Identify existing tools, systems, or databases within the SoHO entity** that could support the collection and centralisation of registration data. Where appropriate, existing tools may be reused for this purpose (e.g. Quality Management System (QMS), vigilance system, traceability system).
4. **Register the SoHO entity** using the system designated by the SoHO National Authority. This may include the EU SoHO Platform, or national registries, as defined in **Article 16** of the SoHO Regulation. Refer to the guidance available on the National SoHO Competent Authority website to confirm the proper procedure for registration. Please note that to register a SoHO entity on the EU Platform, the user must first create an EU Login.(https://trusted-digital-identity.europa.eu). ■

Information Box - SoHO Preparation Authorisations:

As reflected in Recitals 30 and 31 of the SoHO Regulation, regulatory requirements for SoHO preparations should be risk-based and proportionate. Where SoHO entities perform bedside preparations, they may be required to undergo the full SoHO Preparation Authorisation procedure. Furthermore, where SoHO entities apply SoHO preparations prepared and distributed by SoHO establishments, they may be required to cooperate with those establishments, in particular by providing information necessary for risk assessment, including patient risk evaluation and relevant scientific evidence, and, where applicable, by collecting and sharing clinical data generated in accordance with clinical evaluation protocols to support the assessment of safety and efficacy of novel **SoHO preparations**.

For example, non-hospital institutions, such as dental centres or outpatient trauma clinics, may indicate the use of Platelet-Rich Plasma (PRP) for injection in specific clinical indications. In such cases, the non-hospital institution must be appropriately registered and comply with the requirements and recommendations established in this document.
The requirements for the authorisation and registration of PRP as a SoHO preparation, when applicable, will be defined by the Working Group on Authorisation and Assessment of SoHO Preparations and subsequently approved by the SoHO Coordination Board.

Recommendation 6

Involve relevant personnel in the oversight of the SoHO entity registration process

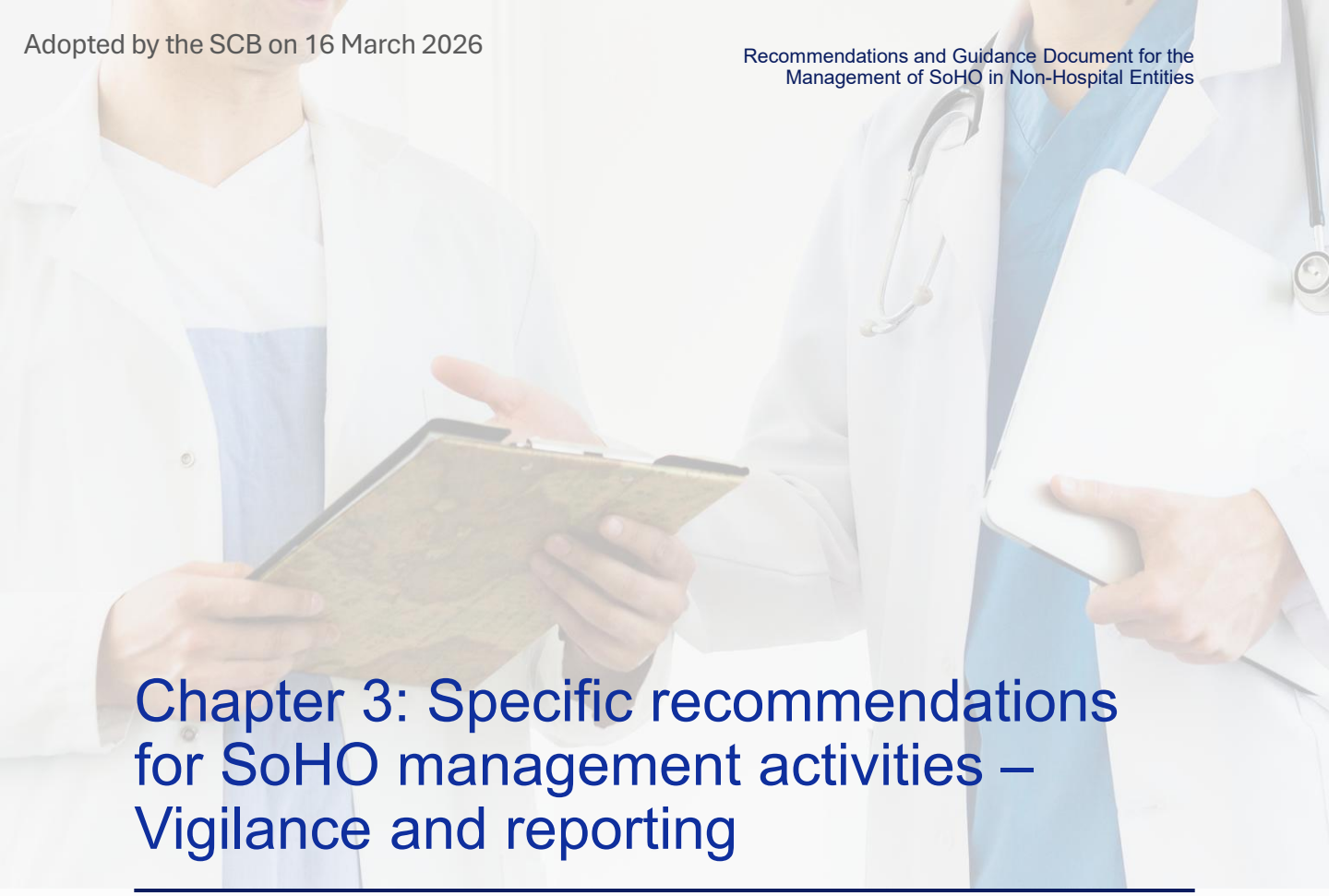
The Responsible Person must be informed of and engaged in the SoHO entity registration process of a SoHO entity. Oversight of this process is essential and may be carried out either by the Responsible Person or by specifically designated persons within the SoHO entity or SoHO establishment, depending on the size of the SoHO entity and the range of activities performed. The responsibility for registration should be documented in the relevant job description or role profile.

The following activities may be undertaken by the Responsible Person or supporting personnel to strengthen registration oversight:

1. **Before submitting, verify** that all **required information is available and that it complies with regulatory standards** and accurately reflects the SoHO entity's activities. For comprehensive details and guidance regarding the information necessary for submission, stakeholders are advised to consult the website of the National SoHO Competent Authority alongside the SoHO Platform.
2. **Notify the SoHO Competent Authorities** and submit updates via the EU SoHO Platform or the tool indicated by the SoHO Competent Authority, **in the event of significant changes** (e.g., modifications to processes, cessation of activities, or organisational restructuring). Information and guidance on how to make a change to the SoHO entity registration can be found on the National SoHO Competent Authority's website and the SoHO Platform.

In addition to the responsibilities of the Responsible Person, a Quality Manager may also contribute to SoHO entity registration oversight by:

1. **Ensuring** that all **required information** (as specified in Article 35) **is available** to meet the registration requirements of the SoHO Regulation.
2. **Tracking updates to SoHO activities, SoHO preparations, processes, or organisational changes that must be reported to the SoHO Competent Authorities.**■



Chapter 3: Specific recommendations for SoHO management activities – Vigilance and reporting

*SoHO entities shall ensure that any suspected serious adverse event or reaction (**Article 3.45 and 3.46 SoHO Regulation**) are reported without delay to the Competent Authority. They must investigate such events or reactions, take corrective and preventive actions, and document the outcomes to prevent recurrence. In this process, SoHO entities shall cooperate with other involved SoHO entities and SoHO authorities to trace and manage risks related to SoHO safety and quality. According to the SoHO Regulation, SoHO entities must establish a system for detecting, investigating, and recording information related to adverse reactions and adverse events. They are also required to promptly notify their Competent Authorities of any suspected Serious Adverse Reactions or Events (SAR or SAE), submitting detailed information and subsequent assessments through follow-up reports as necessary.*

Recommendation 7. Implement a standardised process for Vigilance and Reporting.
Recommendation 8. Ensure proper monitoring and reporting of Adverse Reactions and Adverse Events.
Recommendation 9. Ensure pseudonymisation when sharing data.
Recommendation 10. Involve relevant personnel in the oversight of vigilance and reporting.
Recommendation 11. Gather and use supporting documents to integrate best practices and ensure team's capacities for vigilance and reporting protocols.

Recommendation 7

Implement a standardised process for Vigilance and Reporting

SoHO entities should adopt **standardised processes** for a **prompt reporting, investigation, and mitigation** of **serious adverse events and reactions**. These processes should facilitate timely detection, consistent documentation, and effective communication with competent authorities and other actors involved.

SoHO entities that are not SoHO establishments shall notify the respective SoHO establishments for which they perform SoHO activities on the basis of an agreement, or, where applicable, the SoHO establishment that distributed the SoHO to them, of any serious adverse reactions or serious adverse events. **The SoHO establishments should then report such serious adverse reactions or serious adverse events to the SoHO Competent Authorities**. It is therefore essential to ensure close cooperation, regular exchange, and effective communication with the contractual SoHO establishments (**Article 44(4)).**

In particular, the following aspects shall be ensured:

- **Communication** of all information required in relation to the serious adverse reaction or serious adverse event, taking into account the need to ensure **traceability**;
- **Clarification of responsibilities**: define clear internal roles within the entity for communication with the contractual SoHO establishment, and define designated contact persons on the side of the SoHO establishment;
- Keep relevant contact details **up to date**;
- Ensure that the designated personnel are **appropriately trained** and that there is a clear understanding of which cases qualify as serious adverse reactions or serious adverse events.

In case of doubt, consultation with the cooperating SoHO establishment or the SoHO Competent Authoritie(s) shall always take place. ▶

For non-hospital entities that are SoHO establishments, serious adverse events and reactions shall be communicated to the SoHO Competent Authorities by themselves. The following aspects should then be considered:

1. **Identify existing tools,** systems, or databases within the SoHO entity that may facilitate the collection of vigilance data to be reported (see Article 44(3)). Where available, these tools may be reused for this purpose.
2. **Create SOPs that detail vigilance processes,** handling of incidents, which systems to use and how, personnel responsibilities, reporting timelines.
3. **Enhance end-user engagement** in Vigilance and Reporting (see the definition of end-user in the Glossary of this document, if applicable).
4. **Responsibilities for vigilance and reporting activities should be defined** in job descriptions and internal processes.
5. **Involve relevant personnel**, either the designated Responsible Person or supporting professionals (e.g., biovigilance employees), if feasible, in overseeing the vigilance and reporting activities and ensuring compliance with the SoHO Regulation.
6. **Use standardised forms or templates** provided by the SoHO Competent Authorities or the SoHO Coordination Board to report and document incidents.
7. **Regularly review and update the process for detecting, investigating, recording, and communicating information** concerning adverse reactions and adverse events, considering:
   - National and international guidelines (e.g., EDQM) and best practices for monitoring and reporting Adverse Reactions and Events.
   - Best practices published on the SoHO platform, which guide the reporting of Serious Adverse Reactions and Events related to SoHO.
   - Other EU Regulations relevant to the SoHO activities performed by the SoHO entity, such as the Medical Devices Regulation (EU) 2017/745 or the In vitro Medical Devices Regulation (EU) 2017/746.
   - SOP(s) should have clear responsibilities about reviewing guidelines and updating SOPs accordingly.
8. **Define a procedure for investigating and reporting the detected Serious Adverse Reactions** and/or Events to SoHO Competent Authorities, in alignment with the requirements set out in **Article 44**.
9. **Participate in training** developed by the Competent Authorities (e.g. webinars).
10. **Define a communication protocol and establish communication channels** with the SoHO Competent Authorities.
11. **Use and follow the templates and guidelines provided by the SoHO Competent Authorities** for investigating and reporting Serious Adverse Reactions and Events. Ensure these are aligned with the best practices recommended by the SoHO Coordination Board expert group(s).
12. **Submit the investigation report to the SoHO Competent Authorities without undue delay** following the emergency communication channels previously agreed upon and the defined protocol. The communication should include the information stated in Article 44. The SoHO Competent Authority will verify the information, inform the SoHO entity, and initiate a SoHO rapid alert if necessary.
13. **Define a procedure to remove any SoHO from distribution or use if they are affected, or suspected to be affected**, by Serious Adverse Reactions or Events. SOP(s) should detail this process.■

Recommendation 8

Ensure proper monitoring and reporting of Adverse Reactions and Adverse Events

A lot of non-hospital SoHO entities may be defined as end-users. An end-user is defined as the **individual that applies the SoHO to a recipient**. **Ensuring communication between end-users and involved SoHO entities or SoHO establishment** is crucial in order to ensure proper monitoring and reporting of Adverse Reactions and Adverse Events.

To promote **proper communication**, the following actions may be considered:

1. **Define end-user awareness protocols** aligned with best practices from the SoHO Coordination Board expert group(s). These should outline end-user responsibilities across three key phases:
   - **Initial reporting**: end-users should promptly report any suspected adverse reactions in the recipient or to the offspring of medically assisted reproduction or adverse events to the appropriate SoHO entity.
   - **Collaborative investigation**: end-users should actively contribute to the investigation process by providing clinical insights and relevant medical history to support evaluation.
   - **Final review:** end-users should assist in the final case closure process to ensure that all necessary follow-up actions are completed, including the implementation of any corrective and preventive measures identified during the investigation of Serious Adverse Reactions and Events.
2. **Implement reporting channels** that facilitate submission and tracking of Adverse Reactions and Events by end-users. Ensure the list of contact details (e.g. email addresses, phone numbers) is kept up-to-date and use those for expedited contacts
3. **Provide training and raise awareness** among end-users regarding the importance of their responsibility in reporting Adverse Reactions and Events, and their role in each of the three above-mentioned phases.
4. **Search for relevant external training possibilities**, if available, and keep professionals informed of those. If external training is not available or it is not possible for the professionals to participate in those, internal training could be organised for the staff.■

Recommendation 9

Ensure pseudonymisation when sharing data

Protecting personal information while maintaining the required level of traceability is of utmost importance across all stages of SoHO management, particularly when sharing data related to Adverse Reactions and Adverse Events.

Pseudonymisation *(see the definition in the Glossary of this document)* can be ensured by implementing the following actions:

1. **Replace personal data with pseudonymised codes** in all Adverse Reaction and Adverse Event reports.
2. **Establish a secure system** to link pseudonymised data to original records.
3. **Use existing systems to collect and report pseudonymised data** on adverse reactions and adverse events.
4. **Involve professionals responsible for data protection and GDPR compliance** within the SoHO entity (e.g., the controller, processor and Data Protection Officer) to verify the level of pseudonymisation required for each SoHO activity. The Responsible Person should oversee this verification process.
5. **Where feasible and advisable**, **involve a committee or contact the Data Protection Officer, if available,** to regularly review pseudonymisation practices.
6. **Review and incorporate methodologies or practices from established systems** to ensure robust pseudonymisation. To achieve this, SoHO entities should:

- Assess best practices from these systems, particularly methods for pseudonymising donor data while preserving the traceability required for safety and risk analysis.
- Adapt these practices within the SoHO entity's existing procedures, ensuring alignment with operational needs and regulatory requirements.
- Implement reporting mechanisms that are compatible with the adopted pseudonymisation techniques. ■

Recommendation 10

Involve relevant personnel in the oversight of vigilance and reporting

To ensure compliance with the SoHO Regulation and enhance the effectiveness of vigilance and reporting systems within SoHO entities, it is recommended to involve all relevant personnel in the oversight of vigilance and reporting processes. The oversight of this process can be performed either by the Responsible Person, who must be informed of all the process, or by specifically designated persons within the entity or establishment, depending on the size of the SoHO entity and the scope of activities performed.

The Responsible Person or the designated persons involved may undertake the following actions to ensure effective vigilance and reporting oversight:

1. **Serve as the central point of contact** for vigilance and reporting activities within the SoHO entity.
2. **Coordinate with the Releasing Officer** (as per **Article 49**) or the **Physician** (as per **Article 50**) **of the SoHO establishment**(s) involved in the event of an adverse reaction or event.
3. **Manage reporting processes** with SoHO establishments and Competent Authorities, facilitating communication between clinical teams, SoHO entities, and regulatory bodies to ensure timely and accurate reporting.
4. **Ensure that all staff involved in SoHO activities understand their roles and responsibilities** regarding vigilance and reporting.
5. **Monitor the reporting of Serious Adverse Reactions and Events**, ensuring that thorough investigations are conducted. Where corrective and preventive actions are required, ensure these are properly implemented and followed up.
6. **Clearly document roles and responsibilities** - using an organisation chart and job descriptions.

Training in vigilance and reporting of Adverse Reactions and Events is also important for the professionals involved in this process (see Recommendation 9).■

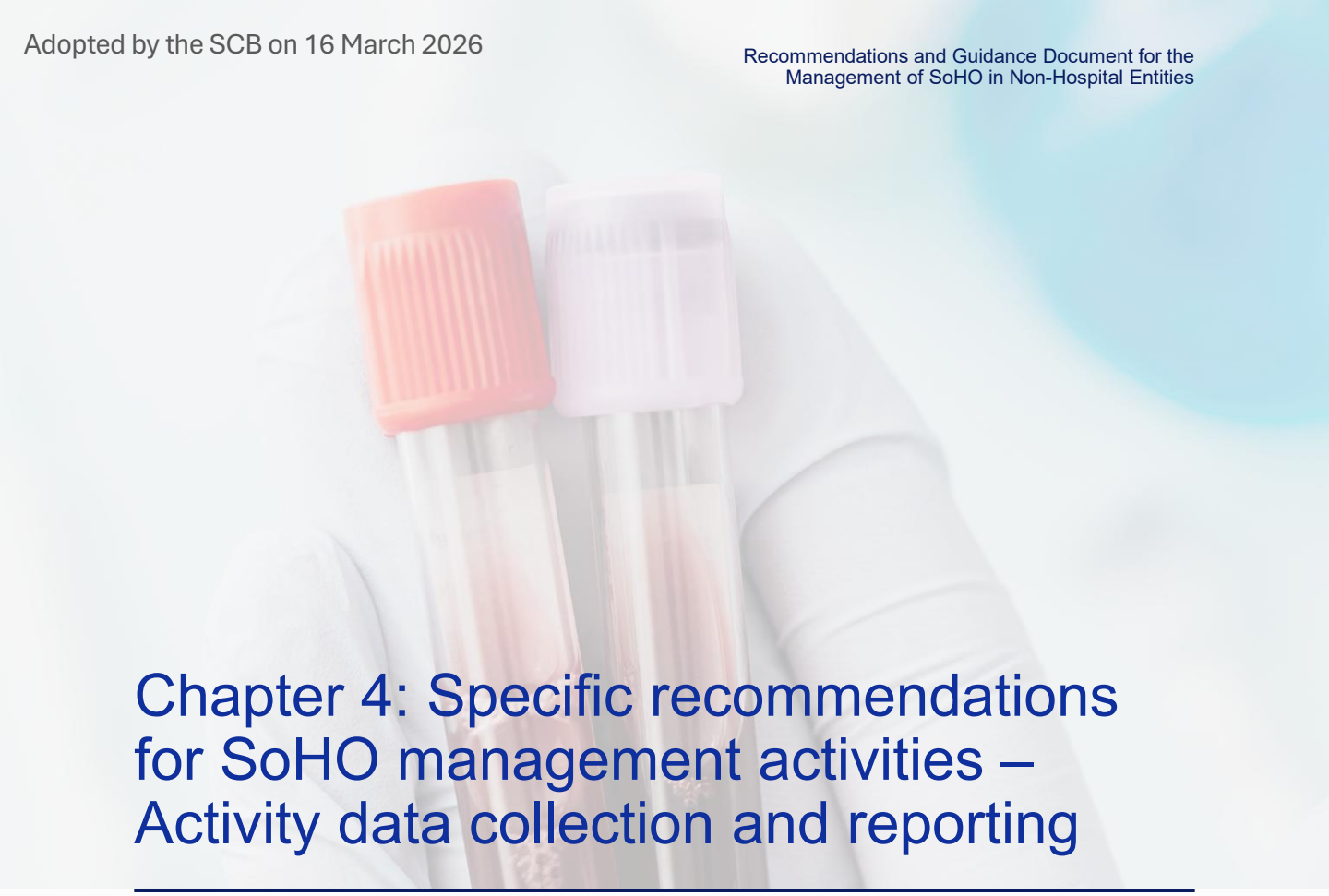
Recommendation 11

Gather and use supporting documents to integrate best practices and ensure team's capacities for vigilance and reporting protocols

SoHO entities should ensure that professionals involved in vigilance and reporting possess the **required skills and are competent** to carry out their responsibilities. To achieve this, it is essential to **provide supporting documents** (which may be facilitated by the Competent Authority), **integrate best practices and offer appropriate training.**

Examples of areas in which it would be relevant to strengthen the team's capabilities through the use of supporting documentation or training include:

1. **Specific data requirements** for reporting adverse reactions and adverse events, including format, timelines, and submission processes.
2. **The roles and responsibilities of stakeholders** in ensuring prompt notification, investigation, and implementation of corrective and preventive actions.
3. **Raising awareness of the importance of timely and accurate reporting** of adverse reactions and adverse events.
4. **Search for relevant external training possibilities**, if available, and keep professionals informed of those. If external training is not available or it is not possible for the professionals to participate on those, internal training could be organised for the staff.■



Chapter 4: Specific recommendations for SoHO management activities – Activity data collection and reporting

Under the SoHO Regulation, SoHO entities are responsible for gathering and documenting SoHO activity data related to the volume of SoHO activities carried out, covering the entire process from SoHO donor registration to human application. SoHO entities are required to submit this activity data in the form of annual reports, following a uniform dataset as specified.

Please note that for example laboratories performing only testing are excluded from the SoHO activity data reporting. SoHO entities that collaborate with each other should coordinate to share data for reporting purposes, thereby avoiding duplication.

Recommendation 12. Implement a standardised process for SoHO activity data collection and reporting.

Recommendation 13. Involve relevant personnel in the oversight of SoHO activity data collection and reporting.

Recommendation 14. Gather and use supporting documents to integrate best practices and ensure team's capacities for internal SoHO activity data collection and reporting protocols.

Recommendation 12

Implement a standardised process for SoHO activity data collection and reporting

To ensure **consistency, transparency, and regulatory compliance** across all SoHO entities, it is essential to implement a standardised process for the collection and reporting of SoHO activity data. A harmonised process not only facilitates accurate monitoring and oversight but supports data-driven decision-making and enhances the safety and quality of SoHO-related activities.

To implement the standardised process, SoHO entities may consider the following actions:

1. **Identify the internal sources within the SoHO entity from which SoHO activity data must be collected and reported**, ensuring alignment with the minimum harmonised dataset (defined by the EDQM and the European Commission, endorsed by the SoHO Coordination Board, and included in the EU SoHO Platform).
   - According to **Article 41(1)** of the SoHO Regulation, activity data to be collected and reported includes information on the following SoHO activities:
     - SoHO donor registration;
     - Collection;
     - Distribution;
     - Import;
     - Export;
     - Human application.
   - The Responsible Person, as per **Article 36**, is responsible for ensuring the collection **of SoHO activity data, maintaining data integrity and consistently meeting the requirements of the minimum harmonised dataset**. This task may be carried out by the Responsible Person or delegated to appropriately trained supporting professionals.
2. **Involve one or more professionals,** including the Responsible Person or supporting staff (e.g., biovigilance employees, if available), to **oversee the SoHO activity data collection and reporting process** (see Recommendation 13).
3. **Identify existing tools, systems, or databases within the SoHO entity or organisation responsible for human application (ORHA)** that can be used to gather all SoHO activity data. Where appropriate, existing tools may be reused for this purpose.
4. **Use the identified tools or systems** (if available) to prepare the annual report based on the collected data.
5. **Submit the annual report by the deadline indicated by your Competent Authority of the following year to the SoHO Competent Authorities** via the tool indicated by the Member State which may be:
   - The EU SoHO Platform (**Article 41(4)**), or;
   - A national or international registry, provided that it collects activity data matching the dataset requirements outlined in the EU SoHO platform (**Article 31(2) and 41(5)**).■

Recommendation 13

Involve relevant personnel in the oversight of SoHO activity data collection and reporting

To ensure data integrity, accuracy, and compliance within the SoHO entity, professionals should oversee activity data collection and reporting. Oversight of this process is essential and may be carried out either by the **Responsible Person**, who must be aware of it, **or by designated persons within the SoHO entity or SoHO establishment**, depending on the size of the SoHO entity and the nature of the activities performed.

Job descriptions of personnel should have clear responsibilities about updating SOPs, data collection and reporting, and organising internal training.

The Responsible Person or designated professionals involved in this process could consider the following actions:

1. **Collaborate with relevant personnel** to collect SoHO activity data (e.g. laboratory head, clinicians, nurses).
2. **Ensure all processes align with regulatory requirements and best practices for SoHO activity data collection and reporting**, as available on the EU SoHO Platform.

Write Standard Operating Procedures (SOPs) to clearly indicate where to find the requirements and detail the steps for data collection and reporting, including the timing and methods.

You may also create easy-to-understand guides, checklists, or diagrams to assist with these tasks

3. **Oversee the timely and accurate submission of data and data updates** to the SoHO Competent Authorities.

You can use for example a reporting calendar with automatic reminders.■

Recommendation 14

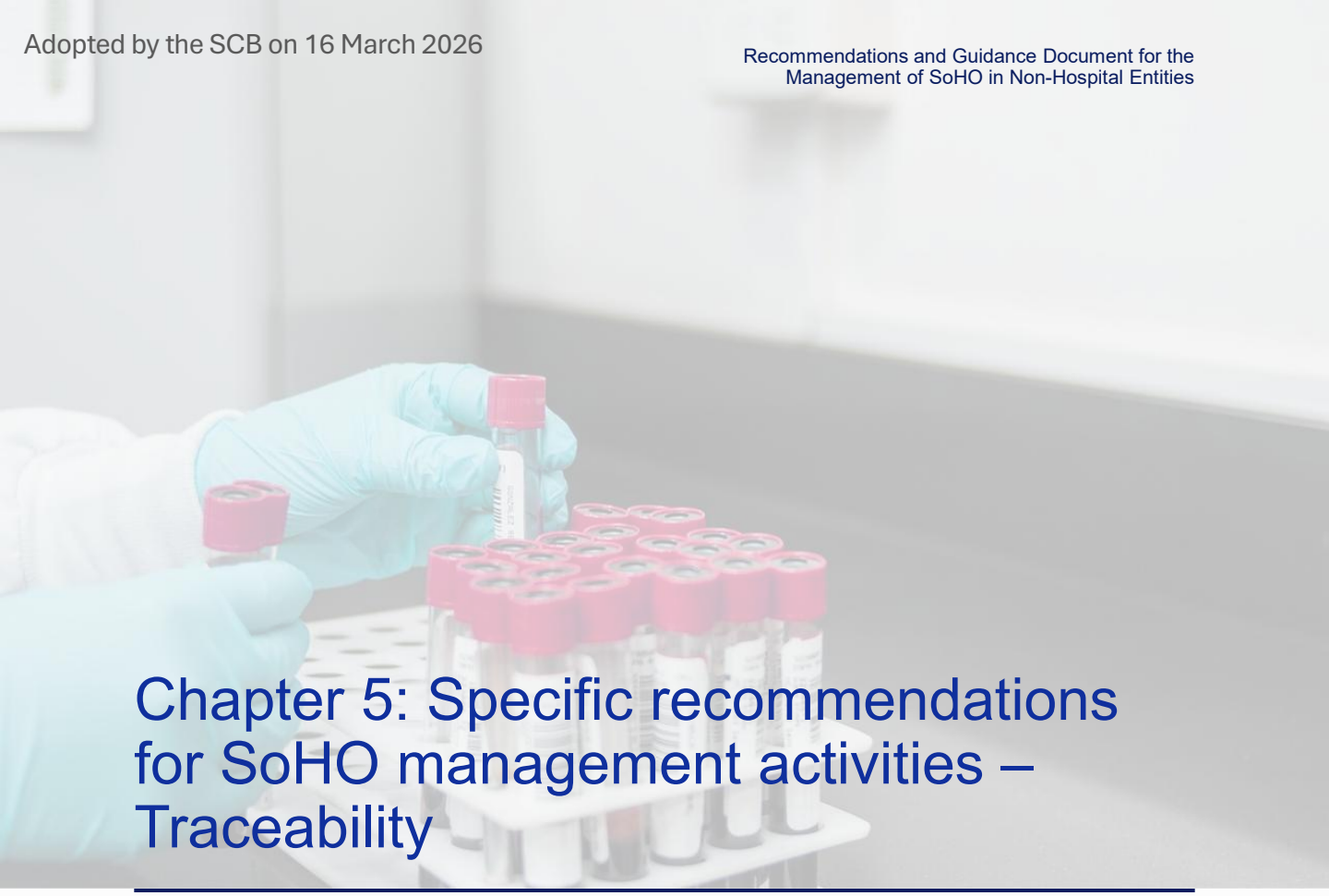
Gather and use supporting documents to integrate best practices and ensure team's capacities for internal SoHO activity data collection and reporting protocols

The use of **supporting documents and integration of best practices**, together with ensuring that **staff are adequately trained**, are essential to ensure those involved in SoHO activity data collection and reporting carry out their tasks effectively. Areas in which it would be relevant to strengthen the team's capabilities through the use of supporting documentation or training include:

- **The data to be collected**, including the minimum harmonised dataset required.

  Have SOP(s) tailored to each SoHO activity performed. They must reflect the minimum harmonised dataset required in accordance with Recommendation 12.

- **How and when the data should be reported,** in line with regulatory timelines, for example:
  - User-friendly guides, FAQs and checklists can be created and used.
  - Visual workflows for data entry, reporting timelines and regulatory deadlines.
  - Reporting calendar with automatic reminders can be used.
  - Participating in training programmes - initial and continued training through for example webinars or webcasts (might be developed by NCA through webinars or webcasts etc.).
- **Roles and responsibilities**, with clear specifications on who is responsible for reporting the data (e.g., the Responsible Person) and to whom it must be submitted.
  - Clearly document reporting roles and responsibilities using an organisation chart.
  - Clearly define tasks and responsibilities, also, their correct understanding should be assessed and recorded.
- **The correct use of the digital tool**, whether the EU SoHO platform or relevant national or international registries.
- Perform internal audit on the topic of activity data collection and reporting. ■



Chapter 5: Specific recommendations for SoHO management activities – Traceability

Traceability and coding are addressed in Article 42 and 43 of the SoHO Regulation. According to these Articles, SoHO entities must implement a traceability system that covers the entire process from donor to recipient. This system must enable the identification and linkage of all relevant data concerning each SoHO donor or the person from whom SoHO are collected for autologous or within-relationship use, to their SoHO and to all the documents, samples, SoHO preparations and SoHO entities that are associated with that SoHO at any point.

SoHO entities distributing SoHO should implement a unique, machine-readable code, which does not reveal the identity of the SoHO donor, and complies with the technical rules of the Single European Code. Application of code shall be on primary package of SoHO, unless their size or storage conditions prevent its application.

Recommendation 15. Get familiar with a Traceability system.

Recommendation 16. Apply the Single European Code.

Recommendation 17. Implement a labelling system.

Recommendation 18. Implement standardised processes to ensure traceability.

Recommendation 19. Involve relevant personnel in the oversight of traceability (if applicable).

Recommendation 20. Gather and use supporting documents to integrate best practices and ensure team's capacities for traceability protocols.

Recommendation 15

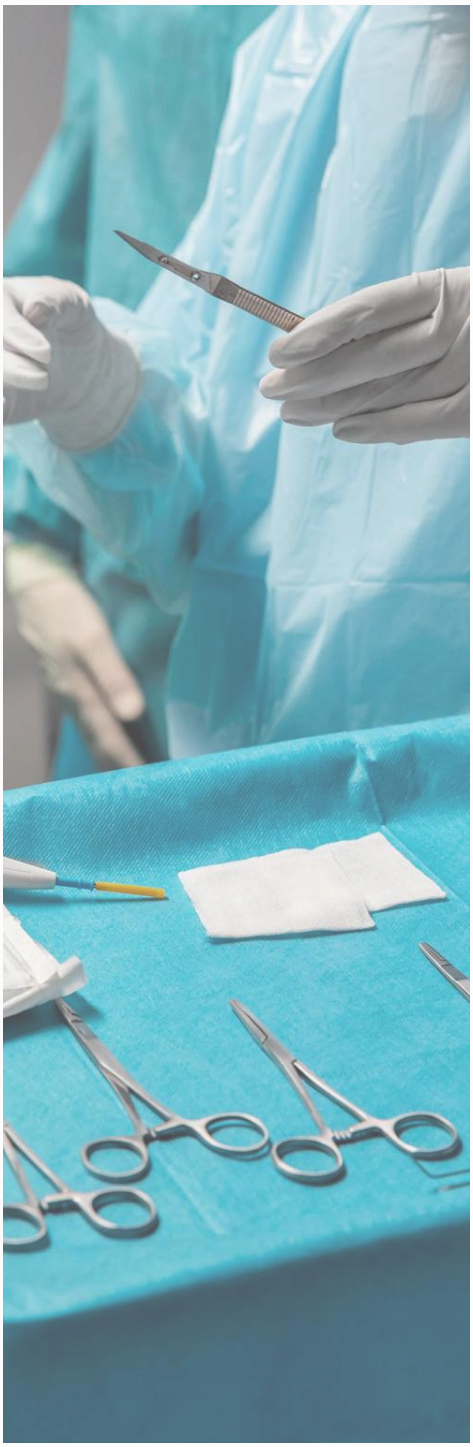
Get familiar with a Traceability system

To ensure linkage between SoHO donor or the person from whom SoHO are collected for autologous or within-relationship use, the corresponding SoHO and all associated documents, samples etc, i.e. to ensure compliance with the traceability requirements outlined in **Article 42** of the SoHO Regulation, the traceability system shall at least include data enabling:

1. **Identification of SoHO donor**
2. **Identification of establishment releasing SoHO**
3. **Identification of SoHO recipient at the SoHO entity applying the SoHO to the SoHO recipient or the manufacturer** of products regulated by other Union legislation, as referred to in Article 2(6
4. **Locating and identification of all relevant data relating to quality and safety of SoHO**
5. **Identification of all materials or equipment that have come into contact with SoHO**

Traceability data shall be appropriately kept, ensuring they are safeguarded and accessible for minimum 30 years from distribution date, date of disposal or exporting date. The data storage may be in electronic form.

If SoHO entity ceases activity, the traceability data shall be transferred to contracted SoHO entity for the remaining time period required. The data transfer should be performed only after informing the Competent Authority. ■



Recommendation 16

Apply the Single European Code

To ensure compliance with the coding requirements outlined in Article 42 and 43 of the SoHO Regulation, **entities distributing SoHO shall apply a code that contains the information required by the traceability system**. For this purpose, the code shall be:

- Unique within the Union
- Machine-readable (unless the size or storage conditions mean that a machine-readable code cannot be applied)
- Not revealing the identity of the SoHO donor
- Compliant with technical rules for Single European Code, SEC (where applicable)

In certain cases, there is an **exemption allowing the provision of only the first part of the SEC** (the donation identification sequence) to be used. These certain cases are if:

- SoHO are transferred for further processing in another SoHO entity
- SoHO are released for manufacturing products regulated by other Union legislation
- SoHO are exported to third countries

The code shall be applied on the primary packaging of the SoHO or on a label attached thereto, or on the documents referring to that SoHO where it can be ensured that such documents accompany the SoHO concerned.

No application of SEC is needed for:

- reproductive SoHO for within-relationship use
- blood or blood components for transfusion or for the manufacture of medicinal products
- SoHO applied to a SoHO recipient without being stored
- SoHO imported into the Union by way of derogation and authorised directly by SoHO competent authorities pursuant to Article 26(6)
- SoHO that are imported to or collected in the same SoHO entity where they are applied.

However, **Article 43(3)** of the SoHO Regulation establishes that the commission shall adopt **implementing acts concerning the format of the Single European Code** and the requirements related to its application to SoHO entities and to SoHO at the point of distribution. **Please note the relevant and currently applicable legal acts and implementing acts of the European Commission concerning the format of the Single European Code** and the requirements related to its application to SoHO entities and to SoHO at the point of distribution. ■

Recommendation 17

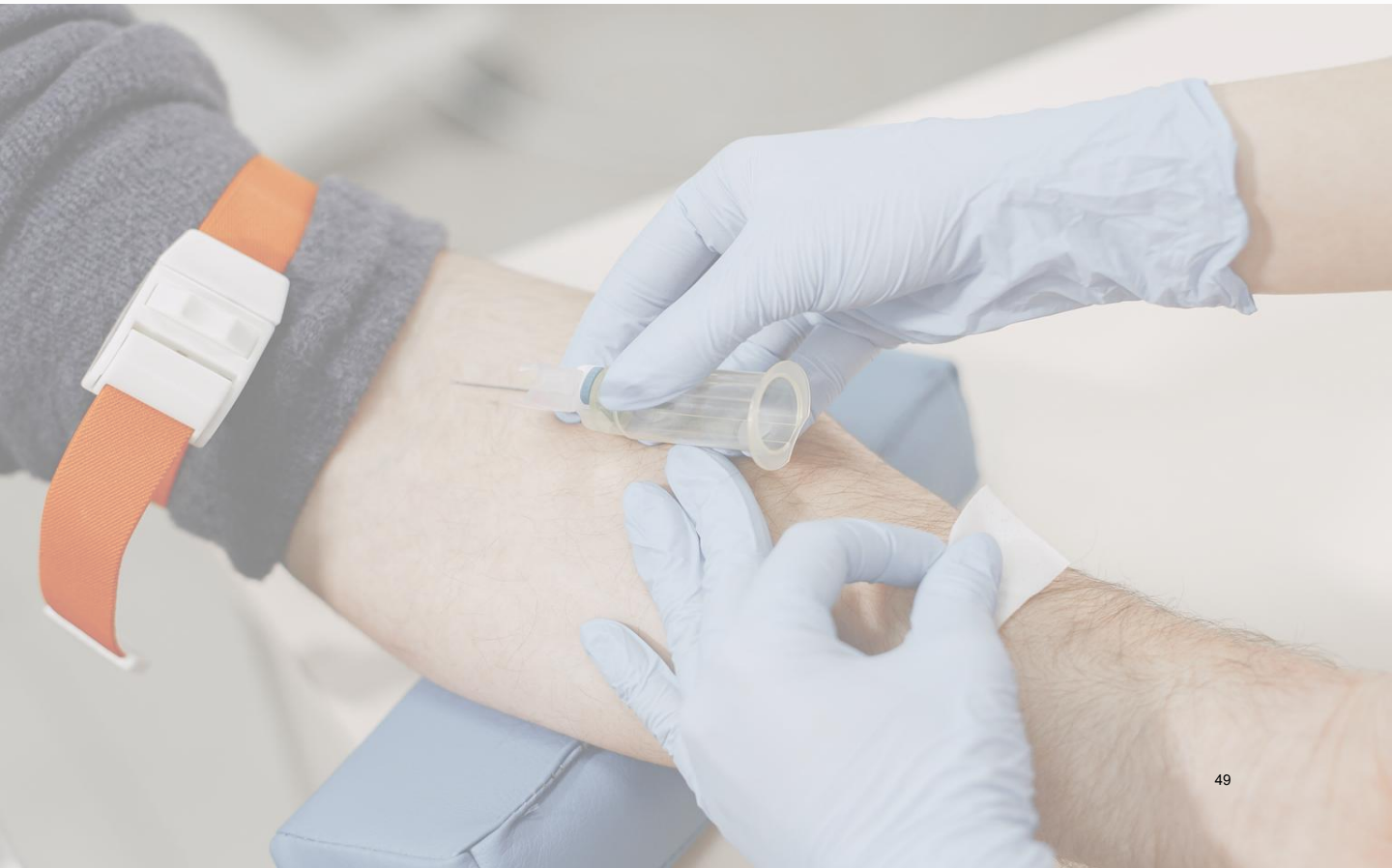
Implement a labelling system

The Single European Code generated for the SoHO shall be applied onto the primary package of SoHO or on a label attached thereto, unless size or storage conditions of SoHO prevent application of code there. Label could also be attached on the documents accompanying the SoHO if it can be guaranteed that such documents will not be separated from the SoHO, or if they will be kept digitally linked to the SoHO concerned.

Application of label shall be performed before distribution of SoHO.

To ensure labelling of SoHO according to requirements outlined in **Article 42, Article 43, Article 56 and Article 59** of the SoHO Regulation, each entity shall implement a labelling system, considering relevant parts of the most recent guidelines. Relevant guidelines to take into account are:

- Technical guidelines, as indicated on the EU SoHO Platform, published by the ECDC concerning the prevention of communicable disease transmission
- Technical guidelines, as indicated on the EU SoHO Platform, published by the EDQM concerning SoHO donor protection other than from transmission of communicable diseases
- Technical guidelines, as indicated on the EU SoHO Platform, published by the EDQM concerning protection of SoHO recipients and offspring from medically assisted reproduction other than from transmission of communicable disease
- Other guidelines adopted by Member States (as referred to in Article 27(6) point (b) in the SoHO regulation)
- Other guidelines or technical methods applied in specific circumstances (as referred to in Article 27(6) point (c) in the SoHO regulation)
- Any relevant implementing acts ■



Recommendation 18

Implement standardised processes to ensure traceability

To ensure full compliance with the traceability and coding requirements outlined in **Article 42 and 43** of the SoHO Regulation, and to promote harmonised, efficient, and secure practices across all relevant settings, SoHO entities should implement standardised processes for traceability. These processes should be designed to support the accurate identification, documentation, and long-term storage of SoHO-related data.

The following actions may be considered when implementing standardised processes for traceability:

1. **Identify existing tools, systems, or databases within the SoHO entity** that could be used to collect traceability data and information related to SoHO. This identification may also support the development and establishment of the SoHO entity's own traceability system (as referred to in Article 42(1)).
2. **Involve one or more professionals** who can anticipate needs of processes and systems to ensure traceability, and who know what data is needed. Use in-house knowledge to ensure all necessary needs and demands are addressed when developing the traceability system and processes.
3. **Apply unique, machine-readable codes** that contain the information required by the traceability system and meet the criteria established by the SoHO Regulation (as per Article 42(3)). The elements of the Single European Code (SEC) shall be applied in cases where SOHO are distributed for human application or where SoHO are transferred for further processing in another SoHO entity, released for manufacture of products regulated by other Union legislation, or exported to third countries (as per Article 43). Other examples include the ISBT128 system (from ICCBBA) or Eurocode.
4. **Use a labelling system that complies with the requirements set out in the technical guidelines published by ECDC and EDQM,** or other guidelines referred to in Article 56(4) and Article 59(4).
5. **Enable electronic reading of SoHO traceability** codes via the SoHO entity's patient databases and/or administrative systems, and ensure this information is linked to patient data.
6. **Establish a secure system for storing traceability data,** ensuring that it is accessible to authorised personnel only and to the SoHO Competent Authority when required**.**
7. **Ensure retention of traceability data** for a minimum of 30 years, mandated by Article 42(6) of the SoHO Regulation.
8. **Develop a contingency plan for the transfer of traceability data to another** contracted SoHO entity, in the event of the original entity ceasing operations. This ensures continued storage, monitoring, and compliance with the SoHO Regulation (Article 42(6)). ■

Recommendation 19

Involve relevant personnel in the oversight of traceability (if applicable)

The **Responsible Person** must be aware of the traceability and coding activities implemented within the SoHO entity. To maintain oversight, the **Responsible Person should either directly supervise the traceability system** or delegate this activity to designated supporting persons within the SoHO entity or SoHO establishment, who must ensure that any **updates or changes are promptly communicated to the Responsible Person.**

The following activities may be undertaken by the Responsible Person or designated professionals to support effective oversight:

- **Ensure that traceability processes and systems are correctly implemented**, including the unique identification of all SoHO and the protection of associated data.
- **Oversee the maintenance and integrity of traceability records** ensuring data is properly safeguarded and accessible to the Competent Authority for a minimum of 30 years, as required by the SoHO Regulation (**Article 42(6)**). ■

Recommendation 20

Gather and use supporting documents to integrate best practices and ensure team's capacities for traceability protocols

SoHO entities should ensure that professionals involved in traceability activities possess the required skills to perform related tasks effectively. To this end**, relevant supporting documents** should be made available, **best practices** should be integrated, and staff should receive **appropriate training** and be formally declared competent.

Areas in which it would be relevant to strengthen the team's capabilities through the use of supporting documentation or training include:

- The application of coding systems to accurately manage SoHO throughout all stages of the process.
- The operation of traceability systems within the specific context of the SoHO entity.
- Privacy and data protection compliance, with a focus on the secure handling of sensitive donor and recipient information in accordance with the General Data Protection Regulation (GDPR). ■

Recommendations and Guidance document for the Management of SoHO in Non-Hospital Entities

Including Small or Single-Department Healthcare Facilities

March 2026