SoHO Coordination Board (SCB)

Recommendation

For the publication of SoHO Preparations in the *SP Compendium* of the EU SoHO Platform

Contents

Acronyms:

EDQM - European Directorate for the Quality of Medicines & HealthCare

EUTCB Directives - Directive 2002/98/EC on safety and quality of human blood and blood components; Directive 2004/23/EC on safety and quality of human tissues and cells

PPD - Preparation Process Dossiers

SCB – SoHO Coordination Board

SP - SoHO preparation

SPA - SoHO preparation Authorisation

WG - Working Group

Objective and Scope

The purpose of this document is to **offer guidance and recommendations to Competent Authorities on managing and publishing information regarding SoHO preparations (SP), introduced into the EU SoHO Platform**.

These recommendations aim to establish a harmonized approach for Member States in implementing the transitional provisions outlined in Articles 82 and 83 of Regulation (EU) 2024/1938 (hereafter referred to as the SoHO Regulation).

The present guidance intends to address various scenarios, including the publication of SPs with varying degrees of complexity and innovation. Additionally, it encompasses the proposed approach to follow for the publication of SP that were not previously covered by Directives 2002/98/EC and 2004/23/EC, specifically blood components from peripheral blood and cord blood for injection or topical use, faecal microbiota, and human milk preparations, as defined in the Article 83 of the SoHO Regulation.

Aspects related to the registration of SoHO entities[1] are not covered in this document, as they will be defined and addressed by the Registration and Authorization Working Group (WG). Similarly, **procedures related to the assessment of Preparation Process Dossiers (PPDs) and the authorisation of SP, during and after the transitional period, are outside the scope of these recommendations**. These will be proposed by the Authorisation and Assessment of SoHO Preparations (SPA) Working Group (based on the outcomes of the GAPP PRO Joint Action[2]) in future recommendations, which the SoHO Coordination Board (SCB) will later adopt.

[1] Recommendations for the registration of SoHO Entities in the SoHO Platform are defined in the guidance produced by the Registration and Authorisation WG of the SCB

[2] GAPP Joint Action (facilitatinG the Authorisation of Preparation Process for blood and tissues and cells) -

The guidance for users—including Competent Authorities and SoHO Entities—on how to use the SoHO Platform, as well as its functionalities for entering and submitting data related to SP, will be detailed in a separate document by the SPA WG.

Introduction

Starting in June 2026, the SoHO Platform will be accessible to Competent Authorities and SoHO Entities, for inputting information related to existing SP, in accordance with the procedures defined at national level—namely, preparations authorized under entities' activities, for each entity in the scope of the previous EU Blood and Tissue and Cells Directives[3], before the end of the transitional period defined in the SoHO Regulation (defined in Articles 82 of the SoHO Regulation[4]).

Competent Authorities should inform SoHO Entities and offer guidance on the national procedures for entering data related to SP into the SoHO Platform. This guidance should include information on timelines and any procedures defined at national level, and information needed to submit existing SP details into the platform. Entities transferred from the current EU Compendium or the Competent Authorities responsible for the verification and publication of Entities' data will also be required to include the information relating to SP currently being distributed.

Based on the information provided by the SoHO Entities, Competent Authorities will determine whether individual SP have been specifically authorised under the activities of the EU Blood, Tissues, and Cells Directives[3] or if additional information is necessary for a proper evaluation of compliance of the SP. After this process, Competent Authorities should assess if the information related to SPs currently being distributed can be published in the new SP Compendium, or if additional information is required (i.e. scenarios where only limited information is available and the Competent Authorities consider that SP cannot be published as authorised). **The current document aims to provide harmonised guidance on how Competent Authorities can perform such assessments**.

Guided by the work of the WGs of the SCB—specifically, the Registration and Authorization, SPA, and Supply WGs—a series of functionalities have been defined in the EU SoHO Platform to meet the legal requirements associated with the registration and authorisation of SoHO Entities and publication of and authorisation of SP.

[3] Directive 2002/98/EC on safety and quality of human blood and blood components; Directive 2004/23/EC on safety and quality of human tissues and cells (EUTCB Directives).

[4] To allow Competent Authorities to fulfil the requirements of Articles 82, SoHO Entities will be invited/requested to introduce information related to preparations resulting from tissue and cell preparation processes designated, authorised, accredited or licensed in accordance with Article 6(2) of Directive 2004/23/EC and Blood components for which SoHO competent authorities have verified their compliance with applicable quality and safety requirements for blood components in accordance with Article 5(3) and Article 23 of Directive 2002/98/EC or with the blood component monographs included in the edition of the Guide to the preparation, use and quality assurance of blood components of the EDQM (European Directorate for the Quality of Medicines & HealthCare) indicated on the EU SoHO Platform on 7 August 2027

However, these functionalities must be used in a harmonized manner by the Competent Authorities to ensure a consistent approach regarding what should be considered authorized (and therefore published as such) before the end of the transitional period.

As the vast majority of Member States did not have a specific system for authorizing SP, the information available beyond activities and SoHO categories is expected to be limited. For this reason, the SPA Module of the EU SoHO Platform is designed to allow, as first step, information to be provided by the SoHO Entities responsible for the processing and storage, and/or distribution (in the case of importing SoHO Establishments) of SP[5]. Alternatively, the SoHO Platform also allows the Competent Authorities to introduce SP data provided by the SoHO Entities in the compendium. SP data will be later validated and, if needed, revised by the Competent Authorities, in a second step (**Figure 1** illustrates the overall flow of information related to this process).

The information required by the Competent Authorities to assess if the SP can be deemed authorised (as defined in Articles 82) and published, shall consider

- the **previous evaluations/authorisations of the SP by the Competent Authority**, namely:
    - if the SP resulting for tissue and cell preparations processes that were designated, authorised or licensed in accordance with Article 6 (2) of Directive 2004/23/EC before 7 August 2027;
    - If the Blood components that were verified by SoHO competent authorities as complying with applicable quality and safety requirements for blood components in accordance with Article 5(3) and Article 23 of Directive 2002/98/EC, or that were otherwise previously designated, authorised, accredited or licensed under national legislation
    - if the SP were otherwise designated, authorised, accredited or licensed under national legislation e.g. on the basis of national guidelines as referred to in Article 56(4), point (b) and (c), and Article 59(4), point (b) and (c) of Regulation (EU) 2024/1938
- their **alignment with the EDQM SOHO Monographs** (or equivalent national guidelines).

Although Competent Authorities have an obligation until August 2028 (Article 82(3)) and Article 87 (2)) to submit the information about the SPs previously authorised under SoHO Entities' activities (referred to in Article 82 (1) and (2)) it will be possible to perform the registration, verification and validation and submission of SPs before this deadline. The same applies to the 'new SP' (SoHO previously excluded from the scope of the EUTCB Directives) referred in Article 83, for which information can be introduced before 8 November 2027, while the Competent Authority conducts the assessment of eventual SoHO Establishment Dossier[6] and/or SoHO PPD.

[5] During the transitional period, the ability to enter SP in the SoHO Platform will be enabled only for SoHO Entities which have been previously validated by the Competent Authority(ies).

[6] Template and guidance on how to submit and assess SoHO Establishment Dossiers will be defined by the SCB (cooperation between Registration and Authorisation WG, Inspections WG and SPA WG of the SCB)

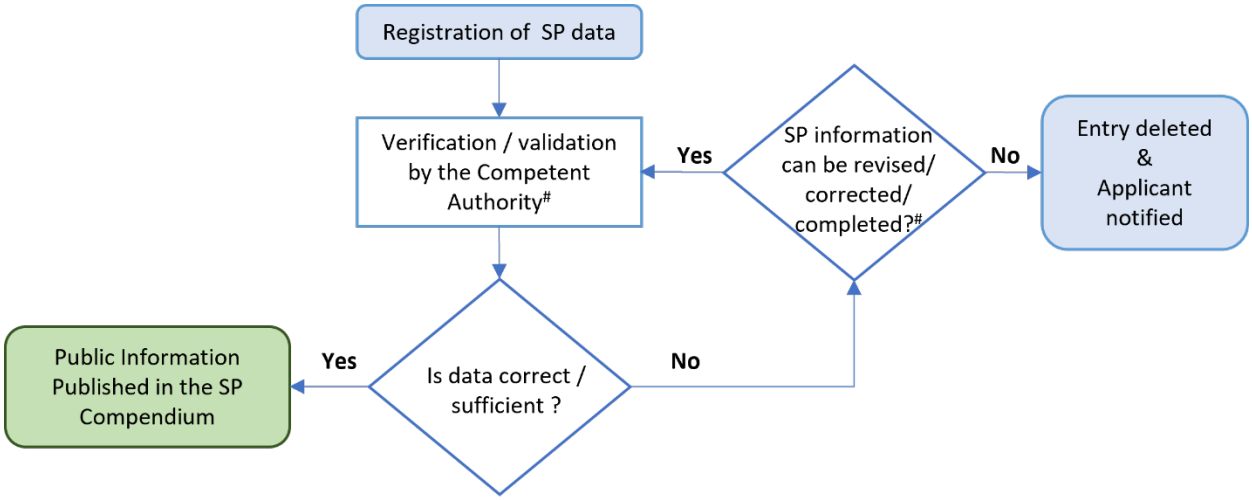


Fig. 1. Overview of the process of for the publication and verification of SoHO Preparations in the SP Compendium of the EU SoHO Platform

Key features of the EU SoHO Platform and other relevant considerations:

- Only verified and published SoHO Entities in the Registration Module of the EU SoHO Platform will have the ability to enable features of SPA Module, for adding SP in the SP Compendium.
- Entities and Competent Authorities can introduce SP only for the SoHO categories included in the published registration of the entity. If a SP is introduced for a SoHO category that is not included in the published registration of the entity, the 'not listed' option is enabled. Selecting this option allows the Entity/Competent Authority to save a draft SP, and generates a notification, informing the SoHO Entity that coordination with the Competent Authority(ies) is required before submitting the request for SP publication.
- Competent Authorities are ultimately responsible for publishing SP information in the SP Compendium (i.e., making the information available to the public).
- PPD features will be activated on the platform only after the transition period ends (i.e., August 2027). However, Competent Authorities may choose to request PPDs from SoHO Entities and conduct their assessments outside of the EU SoHO Platform, during and after the end of the transitional period. Alternatively, the PPD can be uploaded by the SoHO Entity onto the platform. This information will remain confidential and will not be accessible to the public if/when the SP is published in the SP Compendium.
- For new SP or those not fully aligned with EDQM Guidelines and Monographs or national guidelines as referred to in Articles 56 (4) and 59 (4) of Regulation 2024/1938, the GAPP[7] Methodology will assist with the evaluation needed by the Competent Authority, if necessary.

[7] GAPP Joint Action (facilitatinG the Authorisation of Preparation Process for blood and tissues and cells): https://www.gapp-ja.eu/

Recommended methodology for publication of SoHO Preparations in the SP Compendium of the EU SoHO Platform during the transitional period

Step A: Information provided by the SoHO Entity:

Registered and published SoHO Entities (or the Competent Authorities, when Member States decided to follow alternative procedures), will be able to **enter information related to their individual SP**. This functionality is expected to be selected by SoHO Entities or Competent Authorities, after registering SoHO Entities and their activities in the Registration Module of the EU SoHO Platform.

SoHO Entities and Competent Authorities can only introduce SP if its activities are registered and published in the Registration Module of the EU SoHO Platform.

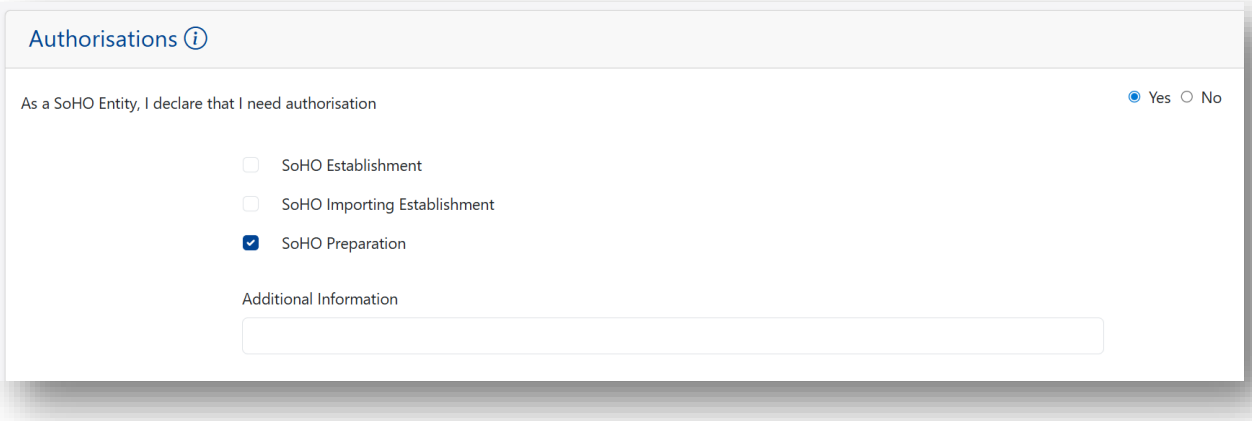


Fig 2. Registration Module – to enable the ability to introduce SP in the SPA Module, SoHO Entities shall declare that they require authorisation of SP.

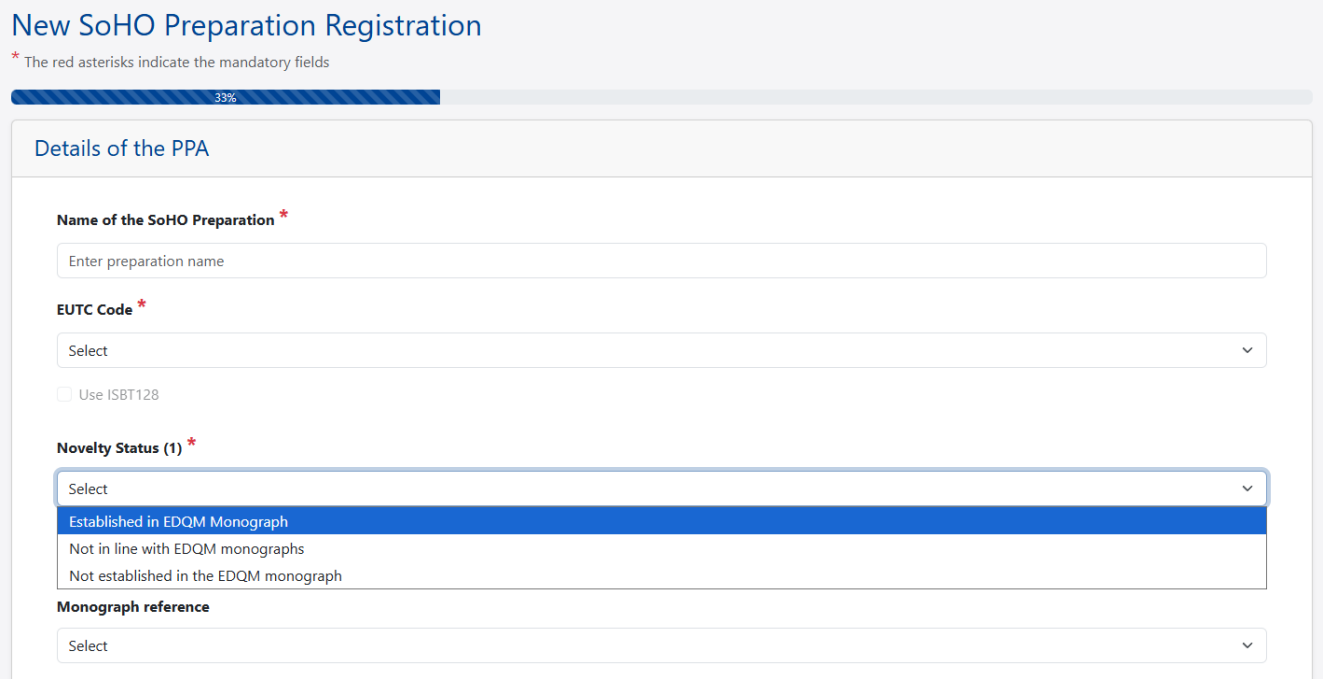


Fig 3. SPA Module – when entering information related to a new SP, the user shall have to provide information about the level of alignment with the Monographs of the latest editions of the EDQM guides or national guidelines as referred to in Article 56(4), point (b) and (c), and Article 59(4), point (b) and (c) Regulation (EU) 2024/1938. 3 options are available: **Established**[8] in the EDQM Monographs, **Not in line**[9] with the EDQM Monographs or national guidelines, **Not Established**[10] in the EDQM Monographs or national guidelines. When the options "not in line with the EDQM Monographs or national guidelines" or "not established in the EDQM Monographs" are selected, an open field will be enabled where the user can provide additional information to justify the authorisation for this preparation.

SoHO Entities or Competent Authorities are also asked to inform (under the field 'Novelty Level (2)') if the SP is authorised ('SP previously authorised (before August 2027)') or is authorised under the Entities' activities in the context of the previous Directives (authorisation 'Included as part of the authorisation of the SoHO Entity under the scope of the previous EUTCB Directives (Transitional Provisions)'). This should identify if the SP is being currently prepared by the SoHO Entity (before the end of the transitional period), or if the information relates to a novel SP, not previously authorised. **Until August 2027, authorised SP are the only SPs to be included in the platform**, as for the remaining SPs, for which Competent Authorities consider that have not been previously evaluated and authorised, the procedures associated to the assessment of requests for authorisation of SP should be managed outside the platform (PPD features of the EU SoHO Platform will not be available, before August 2027)

[8] When all technical specifications and clinical indications (when applicable) of the SP are aligned with the content of the EDQM Monograph
[9] When one or more technical specifications are not fully aligned with the EDQM Monograph (example: different preservation method)
[10] Novel SP which is not described in the EDQM Monographs

Step B: Verification by the Competent Authority

Based on the information provided, the Competent Authority should consider:

- the previous evaluations/authorisations of the SP by the Competent Authority, namely:
  - if the SP resulting for tissue and cell preparations processes that were designated, authorised or licensed in accordance with Article 6 (2) of Directive 2004/23/EC before 7 August 2027;
  - If the Blood components that were verified by SoHO competent authorities as complying with applicable quality and safety requirements for blood components in accordance with Article 5(3) and Article 23 of Directive 2002/98/EC, or that were otherwise previously designated, authorised, accredited or licensed under national legislation
  - if the SP were otherwise designated, authorised, accredited or licensed under national legislation e.g. on the basis of national guidelines as referred to in Article 56(4), point (b) and (c), and Article 59(4), point (b) and (c) of Regulation (EU) 2024/1938
- their alignment with the EDQM SOHO Monographs or national guidelines.

Based on these criteria, the Competent Authority may decide (**Fig. 4** aims to illustrate the decision tree to follow under the different scenarios):

B.1. To publish the SP in the SP Compendium, when:

- The Competent Authority has previously granted specific authorisation for the SP and its clinical indications, under a SP authorisation procedure, before the end of the transitional period;
- The SP is aligned with the EDQM SoHO Monographs or national guidelines **and** aligned with the activities and SoHO Categories previously authorised for that entity and Competent Authority has sufficient available information for the specific SP to verify alignment with EDQM Monograph or national guidelines (i.e. The SoHO Entity selected the option 'Established in the EDQM Monograph or national guidelines' under the field 'Novelty Level (1)' and this statement is confirmed by the Competent Authority. Example: A blood establishment registered on the platform and authorised under the EUTCB Directives to perform the processing, storage, and distribution of platelets provides details of a platelet SP that is recovered, pooled, leukocyte-depleted, and pathogen-reduced, in accordance with the EDQM Blood Monograph).

B.2. To request corrections or additional justification / clarification / data /information, when:

- The information introduced by the SoHO Entity is not fully clear or correct and/or additional data/information is required to verify the SP status, the platform allows the exchange of information, and the Competent Authority may request corrections or additional information to the SoHO Entity. This includes the scenarios where the SoHO Entity selected the option

'Established in the EDQM Monograph' under the field 'Novelty Level (1)', however, after assessment, the Competent Authority finds that this statement is either not entirely accurate or unclear.

- The SP is not fully aligned with or not described in the EDQM SoHO Monographs or national guidelines but has been previously evaluated and authorised (i.e. when the user selected the option 'not in line with the EDQM monograph or national guideline' or 'not established in EDQM monograph or national guidelines but has been previously evaluated). In these scenarios the Competent Authority should assess if the justification provided by the SoHO Entity is sufficient or if additional information is required, before publishing the SP in the SP compendium Example: an SP used for a clinical indication which is not described in the monographs, but for which the SoHO Entity has previously provided sufficient safety and effectiveness data). An open text field within the SP Compendium will be enabled when the user selects any option other than 'Established in the EDQM Monograph' under the field 'Novelty Level (1)'.

Based on the information provided in the two cases above, the Competent Authority may decide to: publish the SP in the SP Compendium as authorised (as described under B.1.) or publish the SP with the status 'Assessment ongoing', while the SoHO Entity is to submit a PPD and/or evidence of safety, quality and effectiveness of the SP (see B.3) .

B.3. To publish the SP in the Preparation compendium with the status 'Assessment ongoing', when:

- The SP follows under one of the scenarios previously described (i.e. B.1 and B.2), but a new clinical indication or a significant change in the SP has been implemented, since the last evaluation by the Competent Authority (i.e. the user selected the option 'not in line with the EDQM monograph or national guidelines' or 'not established in EDQM monograph or national guidelines' and a new clinical indication or a significant change in the SP has been implemented. Example: the SoHO Establishment is authorised to process skin, and adds information related to Acellular Dermis Matrix). In this scenario the Competent Authority should publish the SP with the status 'Assessment ongoing', while the SoHO Entity is to submit a PPD and/or evidence of safety, quality and effectiveness of the SP (recommended deadline for submission of additional information: 8th August 8th, 2028).
- The SP refers to SoHO which were not previously included in the scope of the EUBTC Directives, but where one or more SOHO activities referred to in Article 2(1), points (c)(i), (iv) to (ix) and (xii), of the Regulation were carried out before 7 August 2027. (Examples: SoHO Entities with activities involving blood components from peripheral and cord blood for injection and topical use, FMT or Human Milk), as foreseen in Article 83. For these SP a PPD should be submitted to the Competent Authority until 8th November 2027.
- SPs are introduced by SoHO Importing Establishments, and Competent Authorities consider that additional evidence of equivalence to EDQM technical guidelines are required. (SoHO Importing Establishments will be

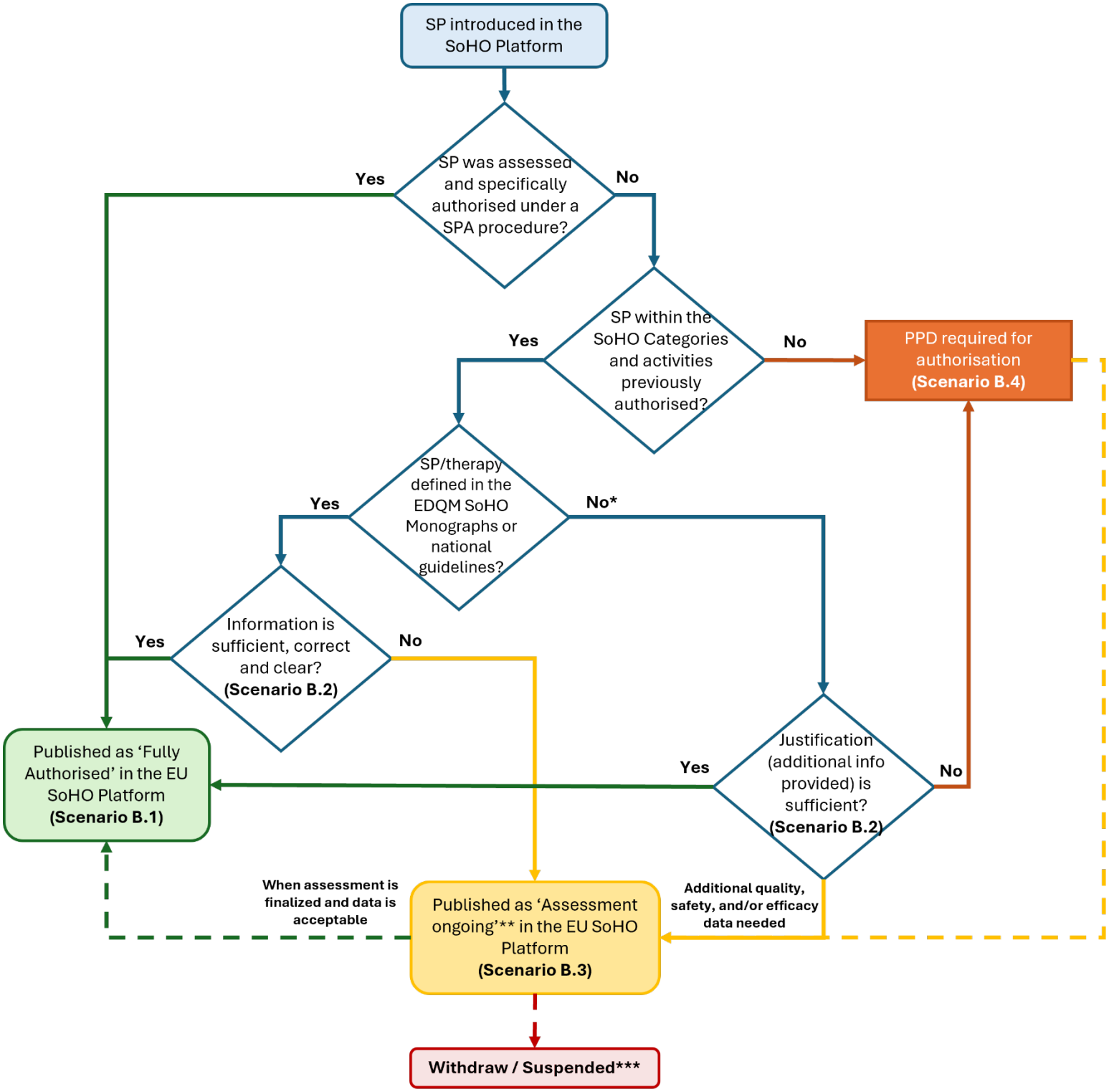
requested to submit SP data until 8th August 2027, for each individual SP, it is recommended that full PPD are requested for all imported SPs.[11])

By publishing the SP as 'Assessment ongoing' while additional safety, quality and/or effectiveness data is gathered, will allow the SoHO Entity to continue distributing the SP (previously under the scope of the previous EUTCB Directives) for clinical application, if no significant safety issues are identified, while the evaluation of additional data is ongoing.

B.4. To request a full PPD and/or update of the SoHO Establishment Dossier, when:

- The SP is described in the EDQM Monographs, but it is not aligned with the activities authorised for the SoHO Entity (i.e. SP is aligned with the EDQM Monograph, but the SoHO Entity is not authorised to process/import/distribute this SoHO category. Example: An ocular tissue bank, authorised to process, store and distribute corneas requests to publish a SP of a cryopreserved pulmonary heart valve allograft). In this scenario, SP can only be introduced if the user selects the option 'not listed' as SoHO category. When the SoHO Entity enter the information in the SP Module, a notification is generated informing the misalignment between the activities authorised and the Competent Authority shall manage the additional authorisations (using SoHO Establishment Dossier and PPD or the templates and procedures defined by the Members States) using alternative means (i.e. outside of the EU SoHO Platform) or uploading these documents under the Registration Module of the SoHO Platform.
- The SP is not aligned with EDQM Monographs and not aligned with the activities for which the SoHO Entity is authorised (Example: a SoHO Establishment, authorised to prepare Musculoskeletal Tissues, introduces information related to vitrified sperm). In this scenario, SP can only be introduced if the user selects the option 'not listed' as SoHO category. When the user enters the information in the SP Module, a notification is generated by the platform, informing the misalignment between the activities authorised and the Competent Authority shall manage the additional authorisations (using SoHO Establishment Dossier and PPD or the templates and procedures defined by the Members States) using alternative means (i.e. outside of the EU SoHO Platform) or uploading these documents under the Registration Module of the SoHO Platform.

[11] PPD to be submitted to the Competent Authority using alternative means until August 2027.



* Or **Yes, but the technical specifications and/or clinical indications not fully aligned**
**i.e. 'Authorisation granted for use under the evaluation of clinical outcome monitoring plan and or while additional data is assessed'
*** Once a SP is published as 'Assessment ongoing' information cannot be deleted. SP/Clinical indication can only be withdrawn or suspended

Fig. 4. Proposed methodology for verification and publication of SoHO Preparation in the SP Compendium of the EU SoHO Platform