

A background image showing a person's hands in a white lab coat, holding a glowing digital network of nodes and lines. The image is overlaid with a blue gradient and a red bar on the left and a green bar on the right.

GAPP-PRO Joint Action

This second release of the GAPP-PRO newsletter provides an overview of the main results achieved between **August 2025 and March 2026**. The initiative continues to play a crucial role in supporting the practical implementation of SOHO Regulation (EU) 2024/1938, **promoting harmonized methodologies and strengthening risk assessment capacities among Member States.**

Index

- 01** Interim meeting
- 02** WP1 – Coordination and Sustainability
- 03** WP2 - Dissemination and Communication of Joint Action (JA) results
- 04** WP3 – Evaluation
- 05** WP4 – Snapshot of SoHO preparation processes in Europe
- 06** WP5 – Pilot-test of GAPP methodology on SoHO
- 07** WP6 – Pilot-test of GAPP methodology for cross-country and joint country assessments
- 08** WP7 – Analysis of pilot test results
- 09** WP8 – Refinement of the GAPP Guideline
- 10** Collaboration with DG SANTE SoHO Team for testing of the SoHO Platform
- 11** Collaboration with the SoHo Preparation Authorisation (SPA) Working Group (WG) of the SoHO Coordination Board (SCB)

 Follow our journey

Interim meeting

► The GAPP-PRO Interim Meeting was successfully held in Rome on October 21st 2025 preceded by a meeting in the presence of the Steering Committee on October 20th 2025.

This second plenary meeting brought together the **leaders of the Work Packages (WPs), representatives of DG SANTE, members of the Consortium, the External Advisory Board and scientific stakeholders.**



During the meeting, the **Report of Competent Authorities (CAs) training needs (D1.2)**, with its main structure and results, and **dissemination activities**, including performance indicators related to websites, LinkedIn, events, and publications, were presented and discussed. Key contents of the **Midterm evaluation report (D3.2)** and a preliminary presentation of the **Analysis Report on the survey results (D4.3)**

were also shared, with feedback collected from DG SANTE and participants. Updates were also provided on **WP5**, with indicators for the GAPP methodology and list of Preparation Process Dossiers (PPDs), and on **WP6**, with PPDs, types of assessments and preliminary results. Finally, the **EUROGTP II** updates relating to Chapters D8.1 and the interactive tool D8.2 were illustrated.

WP1 Coordination and Sustainability

► The Coordination team continues to ensure effective management of the JA, supporting the Consortium in carrying out activities, meeting deadlines, and communicating internally. In recent months, WP1 has provided support via front office and helpdesk, monitored progress through Steering Committee and meetings with WP leaders, and assisted all WPs in preparing deliverables and periodic reports, **ensuring compliance with JA requirements and HaDEA and DG SANTE guidelines**. In addition, the **Report on Competent Authorities training needs has been approved by HaDEA** and it is available on our [website](#).



WP2 Dissemination and Communication of JA results

► WP2 continues to strengthen the visibility of the JA **through coordinated communication and dissemination activities.**

• **Consortium Communication:**

Monthly reminders are sent to update the shared file on activities, ensuring accurate monitoring and reporting.

• **Editorial Plan and LinkedIn:**

Continuous management of the editorial plan with regular publication of content on deliverables, milestones, events and results.

GAPP-PRO representatives actively promote activities, results and initiatives to numerous stakeholders, and the JA is further enhanced through presentations at national and international conferences and scientific contributions, ensuring wide dissemination of the methodology and results.



March 2026

22 — 25

GAPP-PRO participated in the 52° Annual Meeting of the **European Society for Blood and Marrow Transplantation (EBMT)** - Madrid.

WP3

Evaluation

► At the end of the first quarter of 2026, WP3 highlights significant progress under the GAPP-PRO JA. **The Midterm Evaluation Report**, presented in mid-October 2025, analyzes the results of the first 20 months, showing progress in the various WPs and a strong commitment to transparency and continuous improvement. **The evaluation**, based on qualitative and quantitative methodologies and 25 key indicators, **examined the relationship between activities carried out and overall implementation.**

Feedback collected through interviews with WP leaders highlighted **challenges, solutions** and **best practices**. While confirming positive results, the report indicates the need for possible adjustments to timelines to address some delays. WP3 confirms its commitment to overcoming such critical issues and maximising the impact of the initiative.



WP4

Snapshot of SoHO preparation processes in Europe

▶ WP4's activities in recent months have focused on the **Analysis Report on the Survey Results, which has been recently approved by HaDEA**. The analysis highlights that the SoHO landscape is expanding rapidly, with increasingly complex preparations emerging faster than regulatory frameworks can adapt. The WP4 team identified heterogeneity among EU Member States in the application of legal obligations in line with national and EU regulations and the EDQM guide.

The results of the investigation indicate that **a number of types of SoHO** – including blood derivatives, tissues, cells, microbiota and bedside preparations – **are sometimes used without full compliance with regulations**. Risk assessments are performed inconsistently, especially for new or borderline SoHO.

Among the highest-risk categories, preparations without EDQM monographs or a clear regulatory classification were identified, such as vaginal or intestinal microbiota, donated human milk, autologous bedside skin and adipose tissue preparations, and platelet-rich plasma variants.



WP4 produced the **first EU--wide map of SoHO use, risk and compliance**, highlighting the need for harmonised standards under the **new SoHO Regulation (EU) 2024/1938** and systematic training of assessors. The analysis underlines that coordinated EU governance is essential to ensure that innovation progresses without compromising security.

WP5

Pilot-test of GAPP methodology on SoHO

● WP5 has in recent months deepened the application of the GAPP methodology in the different SoHO areas, progressively consolidating the evaluations into a coherent framework. The SWOT analysis has been completed for all sectors except textiles and human milk, laying the foundation for **Deliverable 5.1** (Pilot results on GAPP methodology assessment), currently being developed in collaboration with the experts involved. Important milestones were achieved:



MS17 - Interim reports on the assessment of GAPP tools for identified preparation processes (PPs) per SoHO

that captured the work of the first wave of working groups, completed the indicator card Excel files, and evaluated selected PPDs.

MS18 - Final report on the assessment of GAPP tools for identified PPs per SoHO

marked the completion of the entire set of indicator files in almost all fields, with only the Human Milk Working Group still finalizing its contribution.

MS19 - Identification of strengths and weaknesses of the GAPP methodology

This milestone is being achieved through a dedicated result (D5.1) currently being developed in collaboration with experts involved in SWOT analyses.

WP6 Pilot-test of GAPP methodology for cross-country and joint country assessments

▶ WP6 teams have completed the testing phase of GAPP assessment tools for all fields except for tissues, **marking a significant step toward supporting implementation of the SoHO Regulation.**



MS23 - Cross-country evaluation report

all competent authorities submitted their transnational evaluations, with only the tissue dossier (esophagus transplant) still pending.

MS24 - Joint country evaluation report

all joint country assessment reports have been successfully collected and transmitted to WP7. Observer reports were also collected, completing the picture.

WP6 is now finalizing Deliverable 6.1. The outcome will be shared with the external advisory committee for review, marking the transition from testing to refinement.

WP7 Analysis of pilot test results

▶ WP7 focuses on reviewing the results generated by WP5 and WP6. **Interviews are ongoing with SoHO group coordinators to gather feedback on the GAPP methodology.**

Targeted interviews are also conducted with the appointed coordinators of the transnational dossiers to gather further feedback and analyse the strengths and areas for improvement of the GAPP methodology.

WP8 Refining the GAPP Guideline

▶ **WP8 aims to update the GAPP guidelines** using the results of WPs 5, 6 and 7, while incorporating the new regulatory framework introduced by **SoHO Regulation (EU) 2024/1938**.

A key milestone achieved is the approval of the updated **EUROGTP II risk-assessment tool**, to include breast milk, fecal microbiota and blood components intended for infusion and topical use.

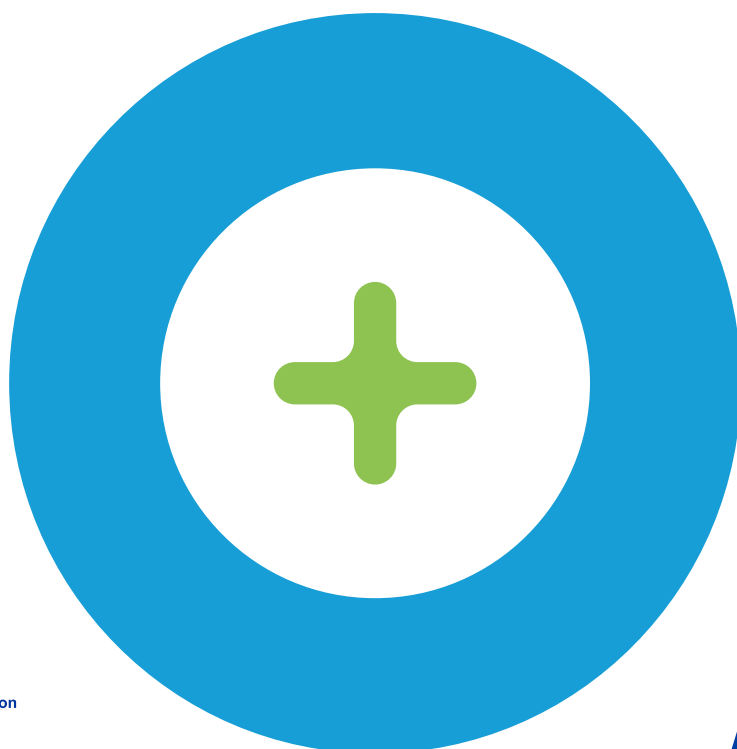
The tool has been submitted for open consultation, allowing competent authorities and scientific societies to test it and provide feedback, ensuring its practical applicability.

Collaboration

with DG SANTE SoHO Team for the testing of the SoHO Platform

• The GAPP-PRO JA continues its cooperation with the European Commission with teams from **DG SANTE** and **DG DIGIT**, through active involvement in the piloting of the EU's next SoHO platform. The Consortium helped test the SoHO Preparation Authorization (SPA) Form, to ensure alignment with regulatory objectives.

These contributions support the development of a platform designed to enable harmonised, efficient and transparent processes across Europe.



Collaboration

with the SPA WG of the SCB

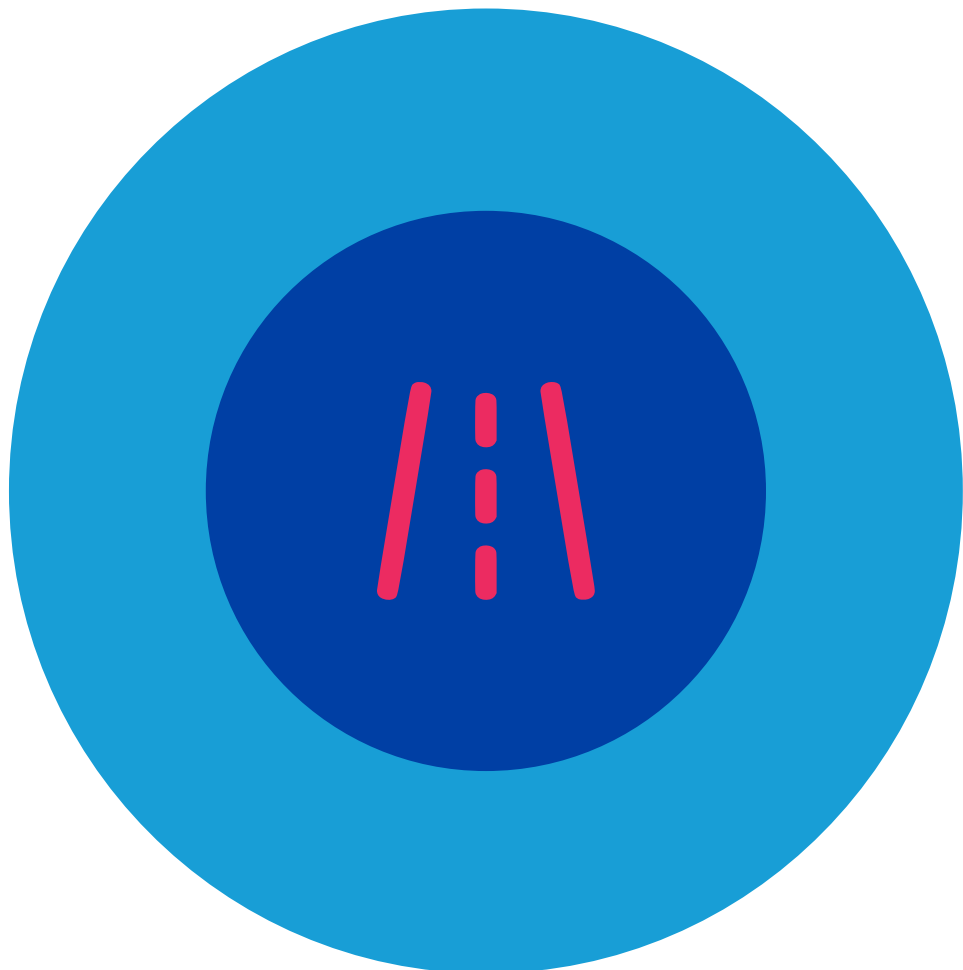
► In addition to the aforementioned activities, the GAPP-PRO Consortium actively **collaborates with the SCB WG on SPA** by:

- **Providing training on the GAPP and GAPP-PRO methodology** to the members of the Working Group and synchronous test of the EuroGTP II tool;
- **Revising and updating templates, procedures and guidelines developed by GAPP** on the preparation, submission and evaluation of applications for SPA, based on the contents and requirements of the new SoHO Regulation, and the outcomes of the pilots;
- **Revising of forms and functionalities** currently being integrated into the platform;
- **Providing guidelines** on how to submit, assess, and authorize SPAs for endorsement by the WG and SCB.
- **Revising of the GAPP-PRO Guidelines** which will include guidance on minimal information/evidence, assessment of clinical data, and joint assessments, based on the outcome of pilots.



Follow

our journey and stay updated through our website and LinkedIn page for news and ongoing activities.





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