Deliverable 1.2 - Report on Competent Authorities training needs

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Work Package	1
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List of Acronyms

B	Blood
CA/s	Competent authority/ies
EEA Countries	European Economic Area
EuroGTP II	Good Tissues and cells Practice II
GAPP	facilitatinG the Authorization of Preparation Process from blood, tissues and cells
GAPP-PRO	Piloting GAPP model approach for assessing and authorizing novel substance of human origin preparation PROcesses
JA	Joint Action
MAR	Medically Assisted Reproduction
MS/s	Member State/s
PPA	Preparation Process Authorization
SIGHTSoHO	strengthening overSIGHT through training and networking on Substances of Human Origin
SoHO	Substances of Human origin
TC	Tissues and Cells

Introduction

The sustainability of the GAPP-PRO methodology and the implementation of the PPA contents included in the new SoHO regulation depend also on both the endorsement of National Competent Authorities to guarantee training to their staff and the maintenance of their skills and on the availability of dedicated EU training programmes.

WP1, in close collaboration with WP4, prepared questions related to training on PPA with the aim to detect the training needs of the CAs. These questions were circulated through the broader survey on SoHO preparation processes at European level, addressing the SoHO CAs, who represented the 27 EU MS, 3 EEA countries (Iceland,

Liechtenstein, Norway) and 1 non-EU country (Ukraine, included as beneficiary of GAPP-PRO JA). The aims of the afore-mentioned survey were, indeed:

- to give a snapshot of both SoHO preparation processes in Europe grouped by different risk levels, including bed-side preparation,
- to detect the state-of-the-art of the organisation of training initiatives on PPA at national level.

1. Objective of the Report

Within this context, the objectives of the Report are:

(1) to map ongoing or planned training initiatives organised at MS level divided per type of SoHO,
(2) to get awareness of ongoing training initiatives dedicated to PPA (European/national/regional/local level),
(3) to detect the potential interest in EU training opportunities.

2. Survey

The survey was divided into five sections (A – E).

- Section A: Contact Information
- Section B: General Information (Blood and blood derived cells; Tissue and cells components; Other not covered above; Blood components for topical use or injection not coveder above)
- Section C: Detailed Information (Collection/procurement; Clinical indications; List of the clinical indications provided)
- Section D: Level risk analysis
- Section E: Training section

3. Methodology

This Report (D1.2) focuses only on Section E on training. Additional information on the other sections is included in D4.3 Analysis Report on survey results.

The survey training section constitutes the structure of this Report. Following the numerical order of the questions in the survey, the tables show the answers to each question.

For confidentiality reasons, the Report does not attribute the answers to the survey to the respective Country or CA. Results will be presented as aggregated or anonymized data and without any link to the respondent.

3.1. State-of-the art

The total number of responding countries is 26, divided as follows:

- 24 MSs,
- 1 EEA Country,
- 1 Non-EU Country.

3.1.1. Ongoing training

Question: ***Do you organise any national training initiatives on Preparation Process Authorisation (PPA) addressed to inspectors/assessors?***

The majority of Countries **do not** currently **organise national training initiatives** specifically focused on Preparation Process Authorisation (PPA).

Only five Countries (19.23%) report conducting such training.

The main reasons cited for the lack of national training include:

- The Preparation Process Authorisation is not currently in place in the country;
- Legal basis for PPA is missing, so it has not been implemented yet.
- Missing or limited financial and human resources;
- Missing or limited knowledge of the topic;

However, several Countries stated that their inspectors participate in training sessions provided by external entities, or that specific training is planned for the near future.

Among those five Countries that organise training, three deliver annual sessions, while one provides induction and advanced training as needed.

As for the methodologies, only three Countries provided the information stating that one organises only residential training, one only blended learning and the remaing one delivers residential, blen4ded and online sessions.

The key topics covered in the aforementioned training sessions are:

- GAPP methodologies, EuroGTP II risk assessment tool,
- National legislation in place, Tissue Establishment activities - donation, procurement, testing, processing, preservation, storage and distribution, accreditation, designation, authorisation or licensing systems,
- Application form and assessment; potential activities; supporting information including validation data; testing information; EDQM guide; information received from European joint action training programmes planned training.

3.1.2. Planned training

Question: Do you plan to organise any national training initiatives on Preparation Process Authorisation (PPA) addressed to inspectors/assessors?

Given the current low level of training provision at national level, 11 Countries **plan to organise** initaitives in the future.

The remaning Countries (15) state that the **main reasons for not planning training** activities at CA level are:

- Budgetary constraints,
- Lack of human and financial resources,
- Outside the scope of the CAs,
- PPA responsibilities are still unclear or delegated externally,
- No legal or regulatory requirement for authorising preparation processes,
- Other institutions, including scientific societies especially for Assisted Reproduction, conduct training.

Among those Countries (11) that plan to deliver training, specifications related to the **frequency** follow in the table below:

Table 1: Number of Countries and number of CAs that organise national training initiatives and related frequency

Frequency	N. of Countries	N. of CAs
Once a year	4	5
When needed	3	3
To be defined	5	6

Among the 11 Countries, only four specified the **topics** as follows:

- How to perform a risk-based evaluation of new preparation processes and indications for SoHO. How to develop clinical monitoring plans for SoHO preparation authorization,
- Assessing the activity license, assessing the change in the current license,
- GAPP methodologies, EuroGTP II risk assessment tool,
- New SoHO regulation,
- Application process and assessment; Potential Activities; Risk assessment (EuroGTP II); Quality; Preclinical studies; Clinical Information; information received from SIGHTSoHO.

3.1.3. Awareness of ongoing training initiatives on PPA

Question: Are you aware of training initiatives on Preparation Process Authorisation (PPA) addressed to inspectors/assessors organised by regional/local actors?

All the responding Countries declared not to be aware training initiatives organised by regional/local actors.

3.2. Training needs

3.2.1. Level of satisfaction of ongoing training initiatives and topics of interest

Question: Do you consider the training provided at national/regional/local level satisfactory to meet the inspectors/assessors training needs?

Regarding satisfaction with training levels at **national, regional, or local levels**, only seven Countries replied positively, the remaining nineteen Countries replied negatively.

Those who provided a negative answer specified the topics in which they deem necessary training or additional training:

Table 2: Areas requiring additional effort

Topic	N. of responses from Country	N. of responses from CAs
Risk assessment	15	18
Quality and safety assessment of products and processes	17	20
Clinical assessment within the context of PPA	14	17
Elaboration of the Preparation Process Dossier (PPD)	13	15
Conditional Authorisation	11	13
Substantial changes	12	15
Interaction of pharmaceuticals like antibiotics /anticoagulants	12	13
Environmental control	10	12

Two responding Countries selected “other” but did not provide clarifications when requested.

3.2.2. Levels of training provided

Questions: Do you provide basic training? - Do you provide advanced training?

Out of 26 responding Countries, 20 report providing basic training related to PPA.

Only nine out of 26 responding Countries deliver advanced training programmes.

No answers on this specific topic were provided by 6 countries.

3.2.3. Maintenance of competences and skills

Question: Do you ensure the maintenance of competences and skills of inspectors/assessors related to Preparation Process Authorisation?

Fifteen (15) Countries ensure training initiatives to maintain staff competencies and skills. Respondents where required to provide specifications on how and why:

Table 3: Number of Countries and number of CAs that organize training initiatives to maintain CA staff competencies and skills

How	N. of Country/ies	N. of CA/s
Through training	3	3
Through SIGHTSoHO	1	1
Through educational seminars, participation in joint actions	1	1
Through regular assessment or assistance in assessing variations and discussion of applications at team meetings. This ensures everyone is reviewing and assessing information in a likewise manner. In light of significant changes from the SoHO Regulation, additional training will be required: • Clinical assessment as part of PPA • Conditional authorisation • Interaction of pharmaceuticals like antibiotics • Elaboration of PPD • Substantial changes - the definition of these changes.	1	1
Through continuous assessment of the performance of staff and Regular further training is mandatory	1	1
Some inspectors were part of EU training initiatives and then they train the other inspectors	1	1
Why	**Country/ies**	**CA/s**
Because maintenance of competences and skills of inspectors/assessors related to PPA is not fully ensured by regional/local level satisfactory	1	1
To provide up to date education on the field	1	1
Because regularly training is needed according to our intern specifications	1	1

The remaining 11 Countries replied negatively specifying the reason/s why:

- PPA is not currently in place in the country
- Lack of human or financial resources.
- Staff turnover is an issue
- Small country size limits available expertise and personnel.
- The belief that maintaining competencies is not within the CA's responsibilities/scope.
- The absence of a mandate to authorise preparation processes.

Question: Do you think that training initiative on Preparation Process Authorisation at EU level should be organised on a regular basis?

Twenty-five out of the twenty-six responding Countries points out the relevance of organising training on PPA at the EU level.

4. SWOT Analysis

Strengths: Training is felt as an urgent need among the responding countries.

Weaknesses: Although induction training activities are common, advanced training and its maintenance is not generally organised by CAs whilst it is more frequently managed, where possible, by the committed staff.

Opportunities: Topics of interest are mostly common among CAs, resulting in the possibility of organising related training.

Threats: The reasons of the lack of training are quite common and also strictly related to decision making at a higher political institutional level. For instance, lack of national funds for acquiring new staff and/or ensuring the training of the personnel already employed; lack of technical knowledge from some CAs on PPA; lack of training and its maintenance may result in low level of quality and safety.

5. General Observations

The analysis results confirm the need to seek a common approach when relating to evaluation and authorization systems throughout Europe. A strategic tool to achieve this goal is the organisation of dedicated continuing education to CAs, especially when dealing with novelties.

Taking into duly consideration of the joint oversight activities contemplated in the New EU SoHO Regulation (EU 2024/1938) periodic EU training of PPA could play a pivotal role in the creation of an ad hoc network of assessors.

Despite the Inspection Guidelines (Good Practice Guideline to authorisation on preparation processes in blood, tissues and cells establishments) already designed the training path needed at CAs level already some years ago, the urgency to receive dedicated national and EU training has becoming every day higher.

The organisation of educational initiatives such as SIGHTSoHO and the forthcoming training on GAPP and GAPP-PRO methodologies (co-organised by the SCB WG on PPA and SIGHTSoHO Tutors) should be encouraged taking advantage of the collaboration among key actors at EU level, eg. SCB WG on PPA.

These results will be taken into consideration in the organisation of future training initiatives.

Annex I - SURVEY SECTION E

Training section

<table>
<tr><td colspan="3">STATE OF THE ART</td></tr>
<tr><td colspan="2">Question</td><td>Answer</td></tr>
<tr><td rowspan="4">a. Do you organise any national training initiatives on Preparation Process Authorisation (PPA) addressed to inspectors/assessors?</td><td>☐ YES</td><td>☐ NO</td></tr>
<tr><td>If yes, how often?
☐ Every month
☐ Every six months
☐ Once a year
☐ Other: _____</td><td rowspan="3">If not, why?
_____</td></tr>
<tr><td>Please, specify the methodology of the initiative:
☐ Residential
☐ Online
☐ Blended
☐ All of the above</td></tr>
<tr><td>Please, specify the topics related to the field of Preparation Process Authorisation (PPA):
_____</td></tr>
<tr><td rowspan="3">b. Do you plan to organise any national training initiatives on Preparation Process Authorisation (PPA) addressed to inspectors/assessors?</td><td>☐ YES</td><td>☐ NO</td></tr>
<tr><td>If yes, how often?
☐ Every month
☐ Every six months
☐ Once a year
☐ Other: _____</td><td rowspan="2">If not, why?
_____</td></tr>
<tr><td>Please, specify the topics related to the field of Preparation Process Authorisation (PPA):
_____</td></tr>
<tr><td rowspan="3">c. Are you aware of training initiatives on Preparation Process Authorisation (PPA) addressed to inspectors/assessors organised by regional/local actors?</td><td>☐ YES</td><td rowspan="3">☐ NO</td></tr>
<tr><td>If yes,
Please specify organiser and frequency
_____</td></tr>
<tr><td>Please, specify the methodology of the initiative (e.g., residential, online…):
_____</td></tr>
</table>

TRAINING NEEDS		
Question	**Answer**	
a. Do you consider the training provided at national/regional/local level satisfactory to meet the inspectors/assessors training needs?	☐ YES	☐ NO If not, please specify the topics on which you deem necessary training or additional training (select more than one): ☐ Risk assessment ☐ Quality and safety assessment (product/process) ☐ Clinical assessment as part of PPA ☐ Elaboration of Preparation Process Dossier (PPD) ☐ Conditional Authorisation ☐ Substantial changes ☐ Interaction of pharmaceuticals like antibiotics /anticoagulants ☐ Environmental control ☐ Others: please, specify_____
b. Do you provide basic training?	☐ YES	☐ NO
c. Do you provide advance training	☐ YES	☐ NO
d. Do you ensure the maintenance of competences and skills of inspectors/assessors related to Preparation Process Authorisation?	☐ YES If yes, why? Please, specify_____	☐ NO If not why? Please, specify_____
e. Do you think that training initiative on Preparation Process Authorisation at EU level should be organised on a regular basis?	☐ YES	☐ NO