



Co-funded by the European Union

APPLICATION FOR AUTHORISATION OF A PREPARATION PROCESS (PPA)

Good Practices Guideline to the Authorisation of Preparation Processes of Establishments Handling Substances of Human Origin (SoHO)

1 EVALUATION PROCESS OF AN APPLICATION FOR A PPA



START OF THE PROCESS



An application for a PPA is submitted

INITIAL REVIEW

Is the application complete?



YES: proceed



NO: return to the applicant

CONTEXT VERIFICATION

Is this activity regulated by Regulation (EU) 2024/1938



YES: proceed



NO: return or terminate the process

RISK CLASSIFICATION

Was the category agreed according to the EUROGTP II tool?



YES: proceed



NO: return for re-evaluation

2 RISK ASSESSMENT



PPA CLASSIFICATION

RISK CATEGORY

- Negligible
- Low
- Moderate
- High

REQUIREMENTS

- Minimal clinical information
- Clinical information + CFupP
- Clinical information + CFupP + CIP
- Clinical information + CFupP + CIP + Comparison (if applicable)

3 RISK-BENEFIT ASSESSMENT



If the risk-benefit ratio is quantifiable and acceptable



Full authorisation

If the risk-benefit ratio is neither quantifiable nor acceptable

Can the risk-benefit be estimated and does the benefit justify the risk?



YES

Authorisation may be granted subject to a plan for monitoring clinical outcomes*, if additional information is provided



NO

Application denied

4 FOLLOW-UP



If an authorisation was granted subject to a plan for monitoring clinical outcomes*

Follow-up information must be submitted

The risk-benefit ratio is then reassessed



Acceptable: Full authorisation



Not acceptable: denied

5 FINAL OUTCOMES



Full authorisation



Conditional authorisation



Refusal of authorisation



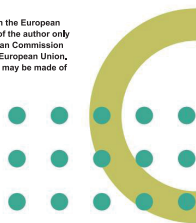
Withdrawn

*In the GAPP Guideline, the equivalent term used is conditional authorisation

© GAPP Joint Action 2022.

This document is part of the Joint Action "785269/GAPP", which has received funding from the European Union's Health Programme (2014-2020). The content of this document represents the views of the author only and is his/her sole responsibility; it cannot be considered to reflect the views of the European Commission and/or the European Health and Digital Executive Agency (HaDEA) or any other body of the European Union. The European Commission and the Agency do not accept any responsibility for the use that may be made of the information it contains.

Translated into English in 2025



RISK ASSESSMENT AND TYPE OF AUTHORISATION

DEGREE OF NOVELTY AND RISK

Defined by the quantity and quality of available data on: **Quality, Safety, and Efficacy**

FULL AUTHORISATION

REQUIREMENTS

- Complete set of data
- Benefit risk ratio quantified and acceptable
- Sufficient evidence to ensure quality, safety, and efficacy



Risk: Negligible (N)



TE: Complies with Quality, Safety, and Efficacy



Follow-up: SARE reports (N)

AUTHORISATION SUBJECT TO A PLAN FOR MONITORING CLINICAL OUTCOMES*

REQUIREMENTS

- Limited set of data
- Benefit risk ratio estimated
- Expected benefit justifies the expected risk
- Further data sets required for final decision making



Risk: Low (L), Moderate (M), or High (H)



TE: Partially complies with Quality, Safety, and Efficacy



Follow-up: SARE reports (L,M,H), CFuP (L,M,H),
CIP (M,H) and Comparison Therapy (H)

REFUSAL OF AUTHORISATION

REASONS

- Insufficient data
- Benefit risk ratio not assessable
- Expected benefit does not justify the risk
- Concerns regarding quality, safety, and efficacy



Risk: Negligible, Low, Moderate, or High



TE: Does not comply with Quality, Safety, and Efficacy

LEGEND

- **TE:** Technical Evaluation (of quality, safety, and efficacy)
- **SARE:** Adverse Reactions and Events
- **CFuP:** Clinical Follow Up Plan
- **CIP:** Clinical Investigation Plan

* In the GAPP Guide[ine, the equivalent term used is conditional] authorisation,

© GAPP Joint Action 2022.

This document is part of the Joint Action "785269/GAPP", which has received funding from the European Union's Health Programme (2014–2020). The content of this document represents the views of the author only and is his/her sole responsibility; it cannot be considered to reflect the views of the European Commission and/or the European Health and Digital Executive Agency (HaDEA) or any other body of the European Union. The European Commission and the Agency do not accept any responsibility for the use that may be made of the information it contains