European Commission

How to process and manage applications for the first authorisation of a PPP in PPPAMS

This quick reference flow chart shows a typical example of how applications for the first authorisation of a PPP are submitted by applicants to National Competent Authorities in PPPAMS. This useful flow chart is easy to follow with step by step instructions that show the overall complete application process and highlights what needs to be done outside of PPPAMS and what needs to be completed in PPPAMS as well as who does what at each stage of the process.

For the first authorisation of a PPP, the product can only be created by the applicant (industry/consultant users).

Getting Started – Processing the first application...

Initial pre-submission discussions between applicant and ZRMS/NCA can occur at any stage prior to registering a product and application in the PPPAMS. These can include meetings and other electronic forms of discussions.

For zonal applications, the applicant should complete the zonal notification form (as in Appendix 3 of the Guidance Document on Zonal evaluation and Mutual Recognition) and confirms the ZRMS (6 months prior to submission.)

① Applicant creates or selects an existing product in PPPAMS.

② Applicant creates a draft application based on this product and selects the zonal rapporteur Member State (ZRMS) and any concerned Member States (CMS).

③ Applicant pre-submits applications including in some cases uploading documents so the ZRMS can see these.

At this stage, the ZRMS can see the pre-submission applications but they do not begin work. It enables further pre-submission contact between the ZRMS and applicant, if required. Meetings and discussions/correspondence may take place between the applicant and the ZRMS/other NCA if necessary.

④ Applicant submits application(s) via the PPPAMS to the ZRMS and an application number is allocated. The CMS are made aware of the application.

Outside the PPPAMS the applicant contacts the NCAs individually regarding sending additional supporting documents and dossiers such as CDs, emails, cover letter, national requirements (application forms etc.) relevant to the receiving NCA and confidential information.

⑤ ZRMS performs validity check.

In the NCA carrying out the validity check the standard processes of that NCA apply including charging and invoicing.

6 NCA either accepts or refuses the application or request additional information if the application is deficient.

7 ZRMS begins evaluation of the dossier and draft Registration Report which is then modified if the application is accepted.

8 NCA can request additional information if the application is deficient. Once the assessment is complete a commenting period is initiated.

If additional information is requested, this is emailed/sent to NCAs by the applicant and the draft Registration Report is made available to NCAs via CIRCABC by the ZRMS and to the applicant.

9 NCA and applicant upload comments and the ZRMS upload the Commenting Tables into PPPAMS.

ZRMS responds to comments received compiling a Reporting Table and updates the draft Registration Report as necessary.

10 NCA decide whether an authorisation can be granted or if the application should be refused and modify the GAP information to reflect the final conclusions of the assessment.

11 ZRMS completes the application (for a zonal application this triggers the start of the applications for CNCA. These NCA follow the same process from validity check until granting of authorisation/refusal.)

12 ZRMS completes the authorisation details in the system, selecting the users to be authorised from the final GAP and modify the classification and labelling to that agreed during the assessment. Even if the application is refused this should be recorded as 'not granted' in the authorisation section.

Registration Report is finalised and uploaded to CIRCABC and sent to applicant. Authorisation is added to Part A. The National Competent Authority produces their certificate of authorisation and publishes this via their national database (if applicable) and makes this available to the authorisation holder.

13 ZRMS publishes the authorisation in the PPPAMS. This becomes publically available in the EU Database.