How to process and manage applications for Mutual Recognition in PPPAMS

This quick reference flow chart shows a typical example of how applications for mutual recognition 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.

Getting Started – Processing applications for mutual recognition...

Initial pre-submission discussions between applicant and Zonal Rapporteur Member State (ZRMS)/National Competent Authority (NCA) can occur at any stage prior to registering a product and application in the PPP System. These can include meetings and other electronic forms of discussions.

1   **NCA has already authorised an existing PPP in the PPPAMS.**

2   **Applicant (or in exceptional cases an NCA) creates a draft application based on the existing authorisation.**

3   **Applicant adds all Member States where the Mutual Recognition (MR) is required and applications are created for those Member States.**

4   **Applicant submits application(s) via the PPPAMS to each NCA and applications to each NCA are activated at the same time. An application number is allocated per NCA.**

Outside the PPPAMS the applicant contacts the NCA 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 can request additional information if the application is deficient and then accepts or refuses the application.**	If additional information is requested, this is emailed/sent to NCAs.
7	**ZRMS begins evaluation if the application is accepted.**	This starts the 120 day period for the Member State to decide whether to grant authorisation or not. NCA evaluate the information submitted/national agenda, where necessary.
8	**NCA can request additional information during the evaluation if the application is deficient.**	Requested additional information is emailed/sent to NCA and documents supporting the PPP are uploaded to CIRCABC.
9	**NCA make decision on whether an authorisation can be granted or if the application should be refused. NCA modify the GAP information to reflect final conclusions of the assessment.**	
10	**NCA complete application, in case of refusal no further action is required.**	If the application is refused, the NCA should include a comment to explain the reasons for refusal when selecting the status 'Application completed'
11	**When authorising the ZRMS completes the authorisation details in the system, selecting the uses to be authorised from the final GAP table and modifies classification and labelling to that agreed during the assessment.**	Part A of the Registration Report is finalised to include the authorisation. Assessment is finalised and uploaded to CIRCABC. The NCA produces their certificate of authorisation and publishes this via their national database (if applicable) and makes this available to the authorisation holder.
12	**ZRMS publishes the authorisation in the PPPAMS. This becomes publically available in the EU Database.**	