How to process and manage applications for emergency authorisations in PPPAMS

This quick reference flow chart shows a typical example of how applications for emergency authorisation are submitted by applicants to National Competent Authorities in PPPAMS. Applicants or users usually have an industry or consultant profile but occasionally National Competent Authorities (NCA) can submit emergency applications on behalf of individuals who for one reason or another do not have their own account.

It is important to note that National Competent Authorities can only create products that will be used for emergency applications. For all other types of applications the product can only be created by the applicant (industry/consultant users).

Getting Started – Processing emergency applications
Important to note: For application for emergency authorisation, the normal status changes that are required for other types of application can be bypassed to enable National Competent Authorities to process the application more quickly.

Initial pre-submission discussions between applicants and National Competent Authorities can occur prior to registering a product and application in the PPPAMS. These can include meetings and other electronic forms of discussions.

1 **Applicant creates or selects an existing product in PPPAMS.**

2 **Applicant then creates a draft application based on this product.**

The applicant must complete the general information, the C&L, GAP and Justification sections.

Further meetings and discussions/correspondence may take place between the applicant and the NCA at this stage and applications may be pre-submitted and documents can be uploaded if appropriate. The NCA can see these pre-submitted applications but do not begin work on them. This enables further contact between the two parties if required.

3 **Applicant sends dossiers and other supporting documents to relevant NCA outside of the PPPAMS.**

This may be a CD or email, for example. These documents include cover letters, confidential information or any other specific requirements plus the supporting dossier for the PPP.

4 **Applicant submits the application to the specific NCA via the PPPAMS and an application number is allocated.**

5 **NCA carries out the validity check and evaluates the dossier.**

Standard processes for charging and invoicing apply for the NCA carrying out the check.

In the event that the NCA requests additional information (this can happen either at validity check stage or during the evaluation stage), you will also receive a notification in PPPAMS and should change the status accordingly when the necessary information has been sent back to the NCA.

If the NCA requests additional studies or information to support the risk assessment it can be emailed/sent outside the PPPAMS.

If the application has been sent back to the applicant due to an inconsistency in documentation sent outside PPPAMS compared to the information in PPPAMS, the applicant may update the application to ensure details within the Classification & Labelling, GAP and Justification sections are correct. Additionally, the NCA may ask for other supporting information. Once any issues have been completed, the applicant then signals that the NCA can continue with the application by changing the status as appropriate.

The NCA will then re-evaluate the information received (if applicable) and either accept or refuse the application.

6 **NCA makes a decision based on their evaluation.**

At this stage, the NCA checks the C&L, GAP and Justification information to reflect the final conclusions of the assessment and changes the status to either 'application completed' or 'application refused' in the PPPAMS.

7 **Authorisation is processed – the NCA produces a certificate of authorisation and publishes this via their national database or webpages (if applicable) and makes this available to the authorisation holder.**

Within PPPAMS, the NCA creates an authorisation record from the submitted application. If an authorisation is granted, the NCA:
- *enters the general authorisation details;*
- *confirms the final C&L;*
- *selects the uses in the GAP that are to be authorised;*
- *amends, if necessary, the Justification tab – the justification tab is the responsibility of the NCA and this must reflect the assessment carried out by the Member State.*

8 **NCA publishes the authorisation in PPPAMS. The applicant, all NCAs, the EC and EFSA are notified and the authorisation becomes publically available in the EU Database of PPPs.**