Import ICSRs: Key differences in old versus new VigiFlow
Key differences – Access to import module

All users can import ICSRs, not only National PV Centre (NC) users.

In new VigiFlow, sub-organisations are able to import E2B-xml files. This was not possible in the old VigiFlow, where only National PV Centres could import.

Only users from NCs could see the module in the old VigiFlow, which meant that only NC’s users could import ICSRs.

Now in new VigiFlow all users will see the module, ie users from sub-organisations can also import ICSRs.
Old and new VigiFlow are based on different versions of the ICH E2B standard, (R2) vs (R3). Imports in new VigiFlow can be done with both formats while the old only handled E2B (R2).

Conversion of formats

When importing E2B(R2) files to new VigiFlow the reports will be converted to E2B(R3) format when saved in the database.

This means that some of the error messages will be expressed referring to E2B(R3). However, a Q&A will be compiled to clarify the error messages.
Key differences – Type of imports

Type of imports

In both old and new VigiFlow there are two options when uploading E2B files, one where strict rules apply and one with looser rules.

In old VigiFlow they are named ‘standard E2B’ and ‘incomplete E2B’, and in new VigiFlow ‘Validated’ and ‘Non-validated’.

Note! when importing E2B(R3) files in new VigiFlow, the only option allowed is ’Validated’ import.
Key differences – Type of imports

Logging of imports

When using the 'incomplete E2B' option in old VigiFlow no logging is made in upload statistics:

In new VigiFlow all uploads are logged, ie also 'Non-validated' uploads will be shown in the import history:
Key differences – Follow-ups

Identification of follow-ups

The two VigiFlow systems identify follow-ups for imported reports in slightly different ways.

New VigiFlow is slightly more strict due to the automatic handling of follow-ups; since no manual verification step is available, this is necessary to avoid incorrect report merging (see next pages).

Old VigiFlow

An imported ICSR is regarded as a follow-up when these two id’s are the same as for an ICSR already in VigiFlow:

• Message sender identifier
• Sender's Safety Report Id

New VigiFlow

An imported ICSR is regarded as a follow-up when these three id’s are the same as for an ICSR already in VigiFlow:

• Sender organisation
• Sender's Safety Report Id
• Worldwide Unique Id
Key differences – Follow-ups

In old VigiFlow, follow-ups are shown in a separate list from which the user needs to manually Promote or Discard the update:
Key differences – Follow-ups

In new VigiFlow, follow-ups *automatically updates* the follow-up reports with the original report that already exists in VigiFlow.

Older versions of the report can be viewed via the Audit trail:

- To open earlier versions of the report click on a Worldwide unique id in the audit trail.

- The latest version updated with follow-up information is shown in the report list.
Key differences – Nullification of report

In old VigiFlow the user needed to manually **Discard nullification** or **Nullify case**:

In new VigiFlow the reports are **automatically deleted** (nullified):