

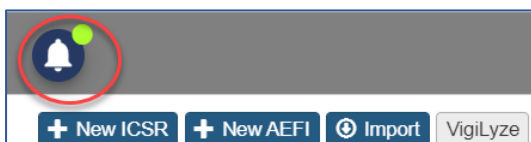
Dear VigiFlow user,

VigiFlow is updated with some new features which we hope you will find useful. A summary of the changes is provided below.

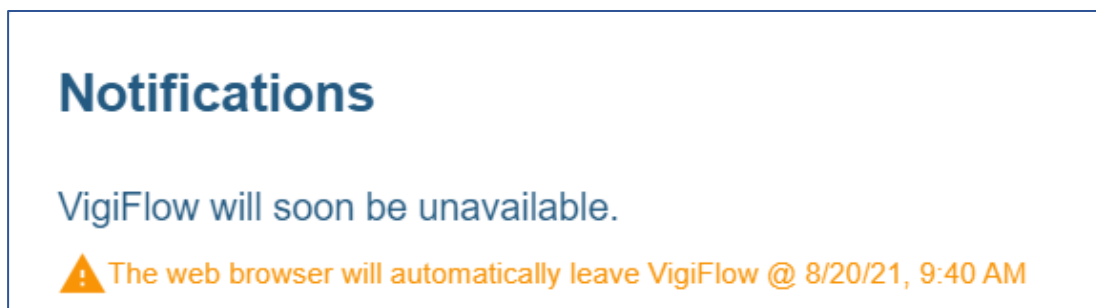
1) Alerts

New process for communication regarding VigiFlow maintenance work and release of new functionality:

- From this release it will be possible for UMC to communicate directly to users through VigiFlow when we plan for downtime connected to upgrade and maintenance work. Approximately 1-2 weeks ahead of the downtime an icon will appear in the upper left corner with a corresponding message.



- Closer to the downtime all users logged-in will receive a pop-up message with details about the exact time when VigiFlow will be unavailable. During the maintenance work, the user will be redirected to a separate webpage containing information about the ongoing work. Any user trying to log-in during this period will also be redirected to the same webpage.

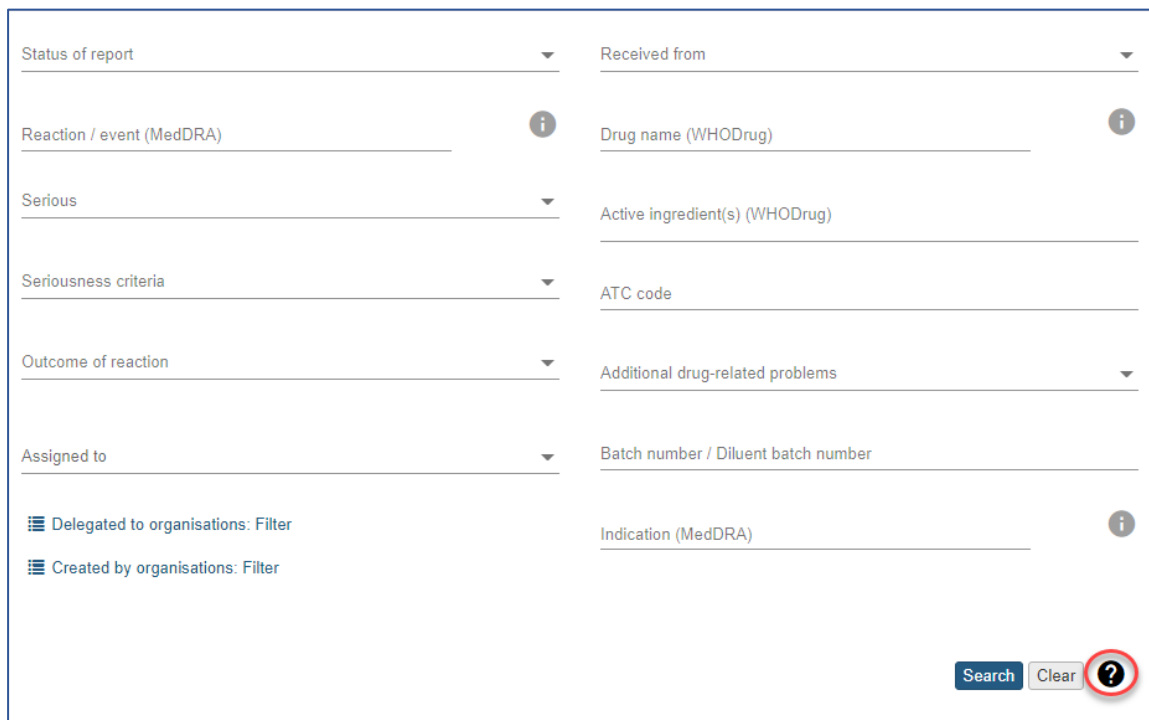


2) Report list

- From this release, reports are by default opened in the form in which they were created. This means a report created in the AEFI form will be opened in the AEFI form also for NC users (which previously had all reports opened in the ICSR form).
- For organisations using the Vaccine eReporting, important to know is that AEFIs sent to VigiFlow from this service will also be opened in AEFI form by default for all users.

3) Report list filters

- The report list filter section has an updated look with a new design. All help texts have been compiled into one place in the filter section.



The screenshot shows a filter section with the following elements:

- Status of report (dropdown)
- Received from (dropdown)
- Reaction / event (MedDRA) (dropdown with help icon)
- Drug name (WHODrug) (dropdown with help icon)
- Serious (dropdown)
- Active ingredient(s) (WHODrug) (dropdown)
- Seriousness criteria (dropdown)
- ATC code (dropdown)
- Outcome of reaction (dropdown)
- Additional drug-related problems (dropdown)
- Assigned to (dropdown)
- Batch number / Diluent batch number (dropdown)
- Delegated to organisations: Filter (checkbox)
- Created by organisations: Filter (checkbox)
- Indication (MedDRA) (dropdown with help icon)
- Search button
- Clear button
- Help icon (circled in red)

- Multiselect checkboxes are added to all filter dropdown menus (except for WHODrug and MedDRA dictionaries), allowing users to search on more than one value in each filter.

4) XML import

Language of reaction / event as reported by initial reporter is set to *Undetermined* for E2B R2 imports.

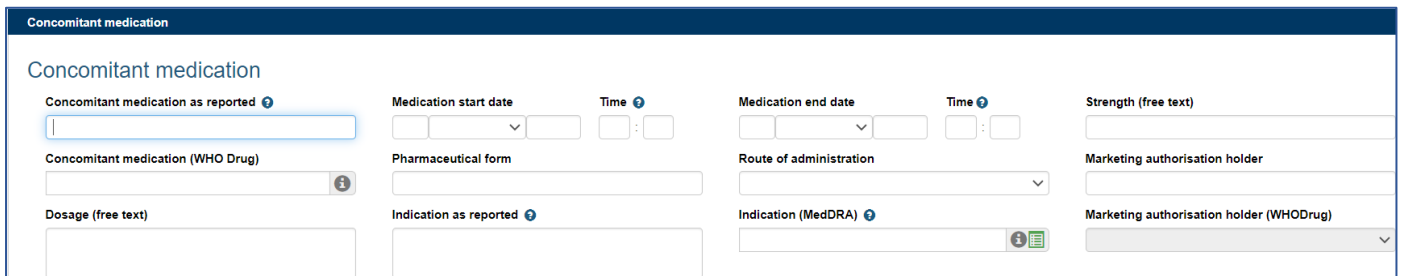
5) Validation changes

When sharing reports with the WHO global database (making them available in VigiLyze), some validations have been changed:

- '*Medical record numbers*' are accepted as an identifier for a patient (although this identifier is not available in VigiLyze).
- '*Reaction / event as reported by initial reporter*' is valid for describing the adverse event (in addition to the MedDRA coded event)

6) Data entry additions affecting the AEFI form

- The fields '*Date AEFI ended*' and '*Duration*' have been added to the AEFI form.
- A separate 'Concomitant medication section' was added to the AEFI form:



The screenshot shows a web form titled "Concomitant medication" with a dark blue header. The form is organized into a grid of fields. The first row contains: "Concomitant medication as reported" (text input), "Medication start date" (date and time pickers), "Medication end date" (date and time pickers), and "Strength (free text)" (text input). The second row contains: "Concomitant medication (WHO Drug)" (text input with an info icon), "Pharmaceutical form" (text input), "Route of administration" (dropdown menu), and "Marketing authorisation holder" (text input). The third row contains: "Dosage (free text)" (text input), "Indication as reported" (text input), "Indication (MedDRA)" (text input with a dropdown arrow and a list icon), and "Marketing authorisation holder (WHODrug)" (dropdown menu).

If you have any questions or comments, please contact vigibase@who-umc.org