Medicine Shortages and Defects Notification Centre User guide

1. Points to consider when working with accounts

An authorised contact person is established for each marketing authorisation holder (or responsible company). When the authorised contact person is registered, they can register themselves and/or other persons as notifier. The MEB will then send the notifiers the login details.

As accounts are linked to marketing authorisation holders, companies or persons submitting notifications for multiple marketing authorisation holders must have multiple notification accounts.

You cannot change the name of the marketing authorisation holder.

The authorised contact person can state on the registration form of a notifier that the notification account is no longer active. In that case, the notifier can log in on the form but cannot submit new notifications. If you are unable to send a notification, first inquire with the authorised contact person whether your account is still active.

2. Overview of notifications

The overview of notifications can be used for the following actions:

- viewing a submitted notification
- copying a submitted notification and using this as a template for a new notification
- completing a notification that was saved in the interim
- completing an entirely new notification form.

Use of icons in the overview of notifications

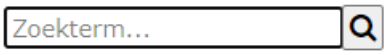
A notification in the overview of notifications can be viewed using the icon showing an image of the completed page. A notification in the overview of notifications can be copied using the icon with the two overlapping documents. An unfinished notification that was saved previously has an icon with the image of a pencil instead of a completed page.

Explanation:

- The details of a previous notification can be copied to be used for a new notification. If the new notification concerns a different type of notification, first remove the checkmark in the copied notification form before selecting the desired type of notification.

Tip: If you copy an existing notification for the same medicinal product to use as a template for making a new notification, the details of the medicinal products do not need to be filled in by hand.

- The button for completing an entirely new notification form is located beneath the overview of notifications. The button is also located at the top of the list if the overview contains more than 24 notifications.
- If the overview of notifications has many notifications, they will be divided over multiple pages.
- If the overview of notifications has more than 24 notifications, this search feature can be found in the top right-hand corner of the overview screen:



- Any notifications that have already been submitted can no longer be removed using the recycle bin icon.
- Any uncompleted notifications that have been saved in the interim *can* be removed using the recycle bin icon. They can also be completed using the pencil icon.
- Notifications in Dutch and English cannot be shown in the same overview.
- A column with the notification reference is now shown as well, without the MPTD 'prefix'.
- All columns can be sorted in either ascending or descending order.

3. Points to consider when submitting notifications

You can use the notification form to submit various notifications. On this page, you will find a number of points to consider when submitting a notification.

Please note: you need to complete a separate form for each medicinal product.

Explanation of the 'Your reference' field:
This field may contain all the information the notifier finds useful. This includes information to distinguish notifications in the overview of notifications. For example:

- the Z index number of the medicinal product;
- the name of the person completing this notification form, if several persons share an account.

For assistance in completing the notification form, please contact the Notification Centre via beheerformdesk@cbg-meb.nl.

For questions about quality defects, you can reach us via the general contact point of the Health and Youth Care Inspectorate:
Telephone: +31 (0)88 120 5000.

Email: meldpunt@igj.nl.

For questions about notifications of supply interruptions, please contact the Medicines Evaluation Board via tekortendefecten@cbg-meb.nl.

At the Medicine shortages and defects notification centre, marketing authorisation holders and manufacturers can submit the following notifications:

- Notification that a medicinal product is being placed on the market for the first time
- Revoke a previously made notification of a supply problem because it will not occur
- Change a previously made notification of a supply problem
- Notification that the marketing of a medicinal product is being discontinued or interrupted
- Notification that a medicinal product is being placed on the market in smaller quantities or to an insufficient degree
- Notification of a quality defect in relation to a medicinal product
- Notification of an out-of-specification in relation to an advanced therapeutic medicinal product (ATMP)

Notifications of a quality defect and an out-of-specification of an ATMP can also be submitted by manufacturers (including compounding and collegiate dispensing pharmacies).

Notification that a medicinal product is being placed on the market for the first time

Explanation:

- Here, you can submit a notification that you will be placing a medicinal product onto the market.
- This notification applies for medicinal products for which you already have a marketing authorisation and is mandatory in this case.
- This obligation does not apply for parallel import marketing authorisations.

Revoke a previously made notification of a supply problem because it will not occur

Explanation:

- Here, you can submit a notification that a previously made notification of a supply problem will not occur.
- The revocation must be submitted before the specified start date of the original notification.

Change a previously made notification of a supply problem

Explanation:

- This is where you can change the start and/or end date of the original notification.

Notification that the marketing of a medicinal product is being discontinued or interrupted

Explanation:

- You should only submit this notification at the level of pharmaceutical form and strength, both for products with a national marketing authorisation (RVG number) and for products with a central marketing authorisation (EU number). This means that you do not need to submit a notification for only one (or part) of the packaging forms/package sizes from a group with the same pharmaceutical form and strength if demand can be met with the other packaging forms/package sizes within the same registration number.
- Here, you can also ask for permission to temporarily supply packaging from another country.

Notification that a medicinal product is being placed on the market in smaller quantities or to an insufficient degree

Explanation:

- You should only submit this notification at the level of pharmaceutical form and strength, both for products with a national marketing authorisation (RVG number) and for products with a central marketing authorisation (EU number). This means that you do not need to submit a notification for only one (or part) of the packaging forms/package sizes from a group with the same pharmaceutical form and strength if demand can be met with the other packaging forms/package sizes within the same registration number.
- Here, you can also ask for permission to temporarily supply packaging from another country.

Notification of a quality defect in relation to a medicinal product

Explanation:

- You can submit this notification for medicinal products with a marketing authorisation, parallel import marketing authorisations and non-registered medicinal products.
- You can submit a joint notification for several strengths and pharmaceutical forms of a medicinal product.
- You must report a quality defect in accordance with Chapter 8 of the EU GMP if it relates to batches of the medicinal product that are on the market and that can result in a recall or an abnormal supply restriction. If you are the manufacturer, you must also report batches that have been marketed elsewhere in the world.

- Quality defects in medicinal products for which a marketing authorisation has been issued via the central procedure must be reported to the EMA and not to the Medicine Shortages and Defects Notification Centre. Please note: you can recognise the authorisation by the EU number instead of an RVG number.
- In the event that medicinal products for which a marketing authorisation has been issued via the central procedure are distributed in parallel, quality defects must be reported to both the EMA and the Medicine Shortages and Defects Notification Centre.

Notification of an out-of-specification in relation to an advanced therapeutic medicinal product (ATMP)

Explanation:

- You must notify an OOS in accordance with EudraLex Volume 4, Part IV, 'GMP requirements for Advanced Therapy Medicinal Products', paragraph 11.5 'Administration of out of specification products'.
- You can submit this notification for both registered and unregistered ATMPs.
- When submitting the notification of an OOS of a registered ATMP, the EMA must also be informed.
- If the ATMP is part of a clinical study, the CCMO must also be informed (via CTIS).
- Timeline: submitting a notification within 48 hours of supplying the product at the request of the attending physician (earlier notification is permitted).
- For questions, see the Q&A on the Health and Youth Care Inspectorate's website, 'Notification of an OOS of an ATMP'.

Notifications in version 3 of the notification form

If you have generated a notification within version 3 of the notification form, you can submit this notification up to 30 November 2024. After this, you will only be able to view your notifications for consulting purposes.