



TB Drugs & Diagnostics Reporting System

How to Report a Shortage or Price Increase

To enter the initial report of a shortage or price increase

Please submit a separate form for each different drug or diagnostic. For example, if you have shortages of isoniazid and ethambutol, complete and submit the form to report the isoniazid shortage. Return to the blank form, complete it, and submit it to report the ethambutol shortage.

However, you can report the following together on the same form:

- A fixed-dose combination drug. For example, if you have a shortage of Rifater, report it on one form even though it includes isoniazid, rifampin, and pyrazinamide.
- Multiple formulations or strengths of the same drug. For example, if you have an ethambutol shortage of both 100 mg tablets and 400 mg tablets, report the shortage of those on the same form.
- A shortage and price increase of the same drug or diagnostic. For example, if you have a shortage of rifampin and a price increase for rifampin to report, report both the shortage and price increase on one form.

Collect the following information

1. **Product:** Name of the TB drug or diagnostic and (if applicable) strength, formulation, package size, manufacturer, and name of the organization from which you procure it
2. **Shortage:** Estimate of the amount of supply left in terms of the number of doses or weeks/months of supply remaining
3. **Price increase:** Price per unit before and after the increase, type of unit on which pricing is based, and invoices documenting the unit price increase (Note: The invoices can be sent with updates if not immediately available. Please provide the most accurate confirmation of the price increases. If you have this documentation, please use for entering the data and consider uploading a pdf of the document for our records.)
4. **Impact:** Data, if applicable (depending upon the type of product) and if available given the time frame. The opportunity to update your report at a future time facilitates the collection of the impact data as we recognize some impacts may not occur until longer after the price increase/shortage started. Impact data includes the following:
 - a. Impact on testing: Groups in which testing is suspended
 - b. Impact on treatment: Delays in starting and completing treatment for TB disease or TB infection, regimen changes, adverse effects
 - c. Impact on staff/budget: Changes in activities, activities to procure the product, and yes/no if staff were diverted from other activities to address the increased volume of calls, etc. related to the shortage

Go to the Reporting Form at

<http://www.surveygizmo.com/s3/1456841/TB-Drugs-Diagnostics-Shortages-Reporting-Form>

or <http://tinyurl.com/oeab5bp>

About this Form Page

This page explains the purpose and target audience and gives instructions. **Click Next** to start entering data.

Contact & Organization Information Page

On this page, enter your contact information and information about your organization.

If this is your first report, click Yes. Your contact and organization information will help us build reports to understand the occurrence of shortages and price increases by type of reporting organization.

If you've already submitted a report, we have your information on file, so **click No** to see the shorter Contact & Organization Information page. **To save you time, we only ask for complete contact and agency information the first time you report.**

[TIP!] Enter the email address to which you want the confirmation email sent.

After you've filled in your contact information, **click Next.**

Initial Report Page

On this page, enter data about the shortage or price increase. Only four fields are required: state, TB drug and diagnostic, issue type, and estimated start date. The other fields requested, however, provide greater specificity that will be useful in our efforts to report out the results and advocate for future solutions to the shortages and price escalations.

State and Region/County/City: Enter the location affected by the shortage/price increase.

TB Drug and Diagnostic:

If you don't see product on the list, click "**Other**" at the bottom of the drop-down list. A blank will appear for you to enter the product's name. Depending on the product selected above, different fields will display below on the form to ask about **strength, formulation, package size, manufacturer, and where it's procured.** Complete as much of the information as you know.

[TIP!] The information above is not modifiable after you submit the initial report, so ensure that it is as complete and accurate as possible.

Date: In case you're reporting after the issue started, the form asks for the estimated date on which the shortage and or price increase began.

Issue--Shortage and/or Price Increase: After the questions about the product, you'll be asked "Are you reporting a shortage, a price increase, or another access issue relating to this TB drug or diagnostic?" Depending on your answer, you'll have questions related to shortages and/or price increases.

[TIP!] You can add new information on supply and price in your subsequent update(s).

After you've filled in the information about the product and type of issue, **click Next.**

Impacts on TB Testing and Treatment and Actions to Mitigate Impacts Page

On this page, enter data about the impact of the shortage or price increase.

The questions about impacts vary depending upon the type of product (diagnostic or drug). In addition, some impacts may not occur until longer after the price increase/shortage started. Answer what you can in the initial report.

[TIP!] You can add to the impact data in your subsequent update(s).

When you're done, **click Submit.**

Confirmation

You'll receive a confirmation message on the Internet and a confirmation email with a summary of your data attached. If you do not receive this, please email TBshortages@tbcontrollers.org.

To enter an update about a shortage or price increase

Collect the following information

1. **Email confirming your initial report** with a link back to initial report data in the form
2. **Shortage:** estimate of amount of supply left in terms of the number of doses or weeks/months of supply remaining
3. **Price increase:** Price per unit before and after the increase, type of unit on which pricing is based, and invoices documenting the unit price increase (Note: The invoices can be sent with updates if not immediately available. Please provide the most accurate confirmation of the price increases. If you have this documentation, please use for entering the data and consider uploading a pdf of the document for our records.)
4. **Impact:** Data, if applicable (depending upon the type of product, test or drug) and if available given the time frame because some impacts may not occur until longer after the price increase/shortage started. Impact data includes the following:
 - a. Impact on testing: Groups in which testing is suspended
 - b. Impact on treatment: Delays in starting and completing treatment for TB disease or TB infection, regimen changes, adverse effects
 - c. Impact on practices: Changes in activities, activities to procure the product, and yes/no if staff were diverted from other activities to address shortage/price escalation issues

Go to the link in your confirmation email.

Updates Pages

On the top of this page is a summary of data from the initial report. The data if these fields of your initial report are not modifiable.

Below the summary is a bullet list of updates to your initial report. **Click to select the update** you want to review or add then **click Next**.

When you're done entering updates to the shortage/price increase data, **click Next**.

To return to the updates list, **click Back**.

Impacts on TB Testing and Treatment and Actions to Mitigate Impacts Page

On this page, the data entered in your initial report are displayed and are modifiable.

Modify and add to your data on impacts.

When you're done entering the impact data, **click Submit**.

Confirmation

You'll receive a confirmation message on the Internet and a confirmation email with a summary of your data attached. If you do not receive this, please email TBshortages@tbcontrollers.org.