



## **TB Drugs & Diagnostics Reporting System**

### **Frequently Asked Questions (FAQs)**

#### **What can I report?**

You can report shortages and/or price increases to TB drugs (used to treat TB disease and TB infection), biologics (which are the purified protein derivative products [PPDs], Tubersol and Aplisol used in tuberculin skin testing for TB infection), and diagnostics like the new interferon gamma release assays (IGRAs) (which are the QuantiFERON and T-SPOT, TB blood tests for TB infection).

#### **For my first report, can I report a shortage or price increase which started some time ago?**

Yes. We want to make this reporting mechanism as comprehensive as possible. We recognize that many of you are currently in the midst of a shortage that likely has not been reported formally as there was no mechanism available to you. You can report shortages and/or price increases to TB drugs that may have started as early as 2012, if you continue to experience the shortage or have recently seen price escalations following the shortage.

#### **Can I report on one form?**

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. Then to report the ethambutol shortage, return to the blank form, complete it, and submit it.

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.

#### **When should I submit an initial report vs. making an update to an existing report?**

Submit a separate initial report for a TB drug or diagnostic reported earlier when there is a shortage or price increase for the following:

- Another state, region, county, or city than on the earlier report

- Another formulation, strength, package size, or manufacturer than on the earlier report

Submit an update when the following occurs:

- The estimated end date of the shortage changes
- Your organization runs out of the product
- The shortage ends
- The price increases for the product you reported to be in shortage

Use the updates comments field to make these updates:

- Change/add the name of the wholesaler, distributor, or supplier
- Change/add the reasons given for the shortage and/or price increase

### **What data do I need?**

#### Initial Report

1. Product: Name of the TB drug or diagnostic and (if applicable) strength, formulation, unit size (package), manufacturer, and name of the organization that you procure it from
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.)
4. Impact: Data, if applicable (depending upon the type of product) and if available given the time frame. (We recognize that some impacts may not occur until longer after the price increase/shortage started.) Impact data include 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 the increased volume of calls, etc. related to the shortage

#### Update

1. Shortage: Estimate of the amount of supply left in terms of the number of doses or weeks/months of supply remaining
2. 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.)
3. Impact: Data, if applicable (depending upon the type of product) and if available given the time frame. (We recognize that some impacts may not occur until longer after the price increase/shortage started.) Impact data include the following:
  - d. Impact on testing: Groups in which testing is suspended

- e. Impact on treatment: Delays in starting and completing treatment for TB disease or TB infection, regimen changes, adverse effects
- f. Impact on practices: 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

### **Can I save and continue?**

No. On the Initial Report, if your computer system crashes or your browser is closed before you click Submit, you will lose the data you entered.

After being submitted, the initial report data are available in read-only summary and for updates on shortage duration, price increases, and impacts.

If you're completing an Update and your computer system crashes or your browser is closed before you click Submit, you will lose the new update data you entered. The earlier data is saved in the system.

### **What happens if the confirmation email is lost and I need to make an update?**

NTCA staff can forward your confirmation email to you within 1 business day if you're the same person who filed the initial report. Please email the name, organization, and email address entered for the initial report to [TBshortages@tbcontrollers.org](mailto:TBshortages@tbcontrollers.org)

### **How will the incoming reports and updates be monitored?**

NTCA staff are notified each time an initial report or update is submitted.

A designated contact at each state TB program will receive an automated report on a monthly basis.

Summary reports will be provided to the NTCA Officers and Board on a quarterly basis.

Summary reports will be provided to the Centers for Disease Control and Prevention (CDC), Division of Tuberculosis Elimination (DTBE), advocacy partners (Treatment Action Group (TAG), RESULTS, and others on a quarterly basis.

Summary reports will be shared with manufacturers of the TB drugs and diagnostics on a monthly basis, at a minimum. More frequent reporting to manufacturers will occur if NTCA staff observes an increase in reporting for a specific drug.

### **How often and where will summary reports of data be posted?**

Summary reports will be posted and available from the NTCA website's home page at [www.tbcontrollers.org](http://www.tbcontrollers.org)

### **How will this data be reported to federal agencies?**

The NTCA hopes to provide real-time data about shortages of TB drugs and diagnostics to our federal partners. This reporting process fills a gap in the existing

mechanisms for alerting federal agencies to the challenges experienced in the field when shortages, and potential price escalations, occur. To date, most reports have been “point in time” survey responses that may be obsolete by the time the data are reported out, as these issues are dynamic, not static.

It is NTCA expectation that the CDC DTBE will communicate the data to other relevant federal agencies in a timely manner.

### **Will community, local public health or state TB program staff input this data?**

The form is open for use by all organizations, public and private, in the United States. The NTCA recognizes that there are many partners in the community who need access to, and use, these drugs and diagnostics. In an effort to have comprehensive, real-time data, we need the input of these individuals, agencies, and organizations.

### **How will this data be reported to state TB programs?**

A designated contact at each state TB program will receive an automated report on a monthly basis. The report will include information about the type of drug or diagnostic reported.

### **Will my contact information be shared? Will my data be anonymous?**

To permit follow-up on issues you report, your contact information will be included in your confirmation email and in reports to your state TB program, so that appropriate follow-up can occur.

However, your contact information will **not** be included in reports given to the NTCA Board or posted on the NTCA website or reports shared with federal partners, other agencies and organizations. Data will be aggregated by other fields such as state, organization type, sector, start date, and issue type.

### **Does reporting in this web-based mechanism assure procurement of the product in shortage?**

No. Reporting a product shortage does not assure that your organization can procure the product. Although the NTCA hopes that the provision of comprehensive, real-time data will reduce future shortages, the report does not trigger a procurement process. The usual communication channel for procurement needs to be followed, based on your organization’s or agency’s procurement process.