

## **Issues that Governments may consider when determining annual legitimate requirements for imports of ephedrine and pseudoephedrine**

1. This document was revised in November 2021 to reflect the main objective of estimating annual legitimate requirements which is to provide the competent authorities of exporting countries with an indication of the amounts legitimately required by importing countries.
2. It is important to note that the presented information is not meant to be exclusive but may have to be applied in combination with other methods, depending on the situation of each country/territory.
3. Annual legitimate requirements for ephedrine and pseudoephedrine include quantities of those substances that may be imported into the country to provide adequate supplies of each chemical for estimated medical, scientific, research and industrial needs; licit export and re-export requirements; and establishment and maintenance of reserve stocks.
4. Once a Government has drafted its annual legitimate requirements for ephedrine and pseudoephedrine, it may wish to publish those estimates and invite relevant parties such as registered manufacturers and importing companies to comment or object to the figures within a certain period of time before finalizing the estimates and providing that data to the INCB.
5. Suggestions for issues to be considered when determining annual legitimate requirements:

- a. Medical needs

Governments can derive medical needs for ephedrine and pseudoephedrine from historical data on:

- 1) Purchases of the substances, including pharmaceutical products containing the substances, by retail establishments, including imports
- 2) Sales of pharmaceutical products containing the substances by retail establishments to patients
- 3) Medical insurance claims related to the substances

Products covered may include both those requiring a prescription as well as those that do not.

The three indicators may be weighted depending on relative importance.

Additional information on medical needs for ephedrine and pseudoephedrine can also be collected from the following sources:

- 1) Population statistics

- 2) Accepted norms of medical treatment, in particular the prescription practices (length of treatment, dosage, etc.)
- 3) Epidemiological profiles (prevalent diseases)
- 4) Type of health services provided

b. Scientific and research needs

Governments can determine the scientific and research needs for ephedrine and pseudoephedrine by collecting historical data on the use of the substances in organic synthesis or chemical analysis in laboratories.

Information on scientific and research needs for ephedrine and pseudoephedrine can be collected from public and private laboratories and research institutions as well as universities.

c. Industrial needs

Industrial needs can be calculated by collecting historical data on use of the substances for the domestic manufacture of pharmaceutical and chemical products.

Information on industrial needs for ephedrine and pseudoephedrine can be collected from chemical and pharmaceutical industries involved in manufacture, distribution, import and export of the substances.

d. Imports and re-exports

Imports and re-exports can be calculated by collecting historical data on imports and re-exports of the substances, including pharmaceutical preparations containing the substances.

Information on total imports and re-exports of ephedrine and pseudoephedrine can be collected from relevant government authorities and chemical and pharmaceutical industries involved in the manufacture, distribution and export of the substances.

e. Reserve stocks

It is generally recommended that an adequate level of reserve stocks is maintained. The required level depends on the needs of the population. For example, the reserve stock can be calculated by taking a certain percentage of the estimated medical and industrial requirements.

Information on requirements for reserve stocks can be collected from chemical and pharmaceutical industries.