

METHODOLOGY MANUAL

for the Regulatory Framework Assessment of the People-Centred Model of TB Care

1. General Provisions

- 1.1 The purpose of this methodology manual (hereinafter referred as Manual) is to provide guidance on how to conduct a regulatory framework assessment of the people-centred model of TB care.
- 1.2 The Manual is an integral part of the self-administered regulatory framework assessment tool (hereinafter referred as RFA tool), which consists of Microsoft Excel based matrix (hereinafter referred as Matrix), the Manual and the reporting format on the results of regulatory framework assessment (hereinafter referred as Reporting Format).
- 1.3 The RFA tool is designed to be used by national stakeholders from TB-REP countries for conducting a comprehensive analysis of their respective national legislation and regulations and identify the level of congruence with the principles of the people-centred model of TB care.
- 1.4 The purpose of the RFA tool is to assess legal-normative acts regulating different aspects of TB care within each country. For the purpose of the assessment, following types of legal-normative acts should be considered:
 - 1.4.1 Laws
 - 1.4.2 Approved national programs, strategies and/or concept papers
 - 1.4.3 Government decrees or ordinances
 - 1.4.4 Orders or ordinances of Ministry of Health, other relevant ministries and agencies
 - 1.4.5 Medical standards, clinical or practical guidelines, manuals, instructions, etc., which are approved by a legal act and thus have a normative nature.

1.5 The RFA tool is intended to be primarily used at the National Tuberculosis Program (NTP) level of each respective country. However, since the tool contains assessment of legal provisions which go beyond the boundaries of TB care, such as financing and medical education, and therefore may require inter-sectoral cooperation, it is recommended that the implementation of the RFA tool shall be administered at Government level, which will enable involvement of all relevant stakeholders (hereinafter referred as Users) from Ministry of Health, Ministry of Education and/or other relevant agencies, such as health financing authority (where applicable), etc.

1.6 For implementation of RFA tool the Users shall first get familiar with this Manual, second, fill in each component table in the Matrix, and third, based on the information provided for each component, compose the final report, based on the provided Reporting Format.

2. Structure of the RFA Matrix

2.1 The RFA Matrix is organized into sections, subsections and components. The Matrix contains a "Home" sheet, which serves as Table of Contents and helps to easily navigate across different components, separate sheets for assessment of each component, as well as a "Summary Table" sheet, which is automatically filled in upon entering the data in each component's table. Users are not supposed to directly enter or manually modify any information in the "Summary Table" sheet.

2.2 Sections of the Matrix reflect the following major areas of TB policy and regulation:

1. National TB strategy
2. Organization of TB care, which is divided into three subsections, reflecting main types of TB care:
 - A. Prevention (promotion and protection)
 - B. Detection and diagnosis
 - C. Treatment and support.
3. Health workforce in TB
4. Financing of TB services.

2.3 Each section of the Matrix is further divided into components. There are total of 30 components in the Matrix. The components are the main elements of the RFA tool, that are subject for assessment. The basic criteria for designating a topic (or an issue) as a separate component is

whether that issue is regulated (or, typically, can be regulated) by a separate legal-normative act (or acts).

2.4 For assessment of each component the Matrix contains standardized sheets, which must be filled by the Users. Besides standard questions that are the same across all components, each sheet contains also some component-specific questions, which reflect the main aspects of the people-centred model of TB care relevant to the particular component.

3. Using the RFA Matrix

3.1 After opening the Microsoft Excel file (only for the first time) Users must first activate “Enable the editing” mode. Then they should enable the macros by pressing the "Enable content" button at the top. In order to be able to use the Matrix, Users need to have the latest version of Microsoft Excel installed (Excel 2016 or newer), and it is recommended to use the English version of the software.

3.2 Users can select the component they want to work on by one of the following options:

3.2.1 Clicking on component's title in "Home" sheet, or

3.2.2 Pressing the "Back" or "Next" buttons at the bottom of each sheet (which will take them either to previous or next component), or

3.2.3 Clicking on the tab of a particular component at the bottom of the file.

3.3 For ease of navigation, each component sheet also contains the following buttons:

3.3.1 "Home", which redirects to the "Home" sheet,

3.3.2 "Summary", which redirects to the "Summary Table" sheet,

3.3.3 "Reset", which clears the content of the sheet and allows the user to start filling it again.

3.4 In case a particular component is regulated by more than one legal-normative act, they must be listed in a hierarchical order (i.e. first the laws, then the Government decrees, followed by Ministerial orders etc.) in the same sheet. All required information for each of these acts (the date, the number etc.) must be filled in the relevant fields in the same order.

3.5 In case the same legal-normative act regulates two or more components, the same basic information about the particular legal act should be entered into all relevant sheets.

3.6 In case the subject matter legal-normative act has been amended or changed after its initial approval, Users shall refer to its latest (current) version. There is no need to reflect other legal acts in the Matrix by which the amendments and changes have been made to the main document.

4. Filling in Component Assessment Tables in the RFA Tool Matrix

4.1 Each component's assessment table contains the title of the component, seven questions (Q1 to Q7) and a "Component Summary" field.

4.2 "Q1. Is the aforementioned component regulated by a legal-normative act?"

The purpose of this question is to find out whether the particular component of people-centred model of TB care has legal regulation or not.

Either YES or NO should be selected.

If the answer for the Q1 is YES, then the User must go to Q2 and address all remaining questions, except for Q6.

If the answer for the Q1 is NO, then the User must skip Q2 to Q5 and jump to Q6.

4.3 "Q2. If YES, is it specifically related to TB care, or has a general nature (i.e. covers different areas of health care delivery)?"

The purpose of this question is to find out whether the legal regulation of the particular component covers only TB care, or also other areas of health care delivery system.

Either YES or NO should be selected.

If the answer for the Q2 is YES (i.e. the regulation is related only to TB care), then the User must skip the Q3, go to Q4 and then address all remaining questions, except for Q6.

If the answer for the Q2 is NO, (i.e. the regulation covers different areas of health care delivery), then the User must go to the next question and then address all remaining questions, except for Q6.

4.4 "Q3. If the answer to the previous question is NO, then please indicate whether there is a need to have a TB-specific regulatory act for this component?"

The purpose of this question is to find out whether Users think that the particular component of TB care needs separate legal regulation or not.

Either YES or NO should be selected. If needed, Users can provide additional comments to clarify or justify their answer to this question in "Component Summary" field.

4.5 "Q4. Please provide the following information on the regulatory act:

Q.4.1 Full title of the document

Q.4.2 Approving authority

Q.4.3 Document date (day, month, year)

Q.4.4 Document Number (or Reference Code):

Q.4.5 If available, please provide the online link to the document."

The purpose of this question is to provide full reference information for the particular legal act.

Users must fill in relevant information for each question in the provided field.

4.6 "Q5. Does the aforementioned regulatory act address the following elements of the People-Centered model of TB care?"

The purpose of this question is to find out whether the current legal regulation adequately reflects main elements (or aspects) of people-centred model of TB care.

Users must address each specific question in the table by selecting YES or NO, using the actual text of the legislation or regulations. If they select YES for any element, then they also must provide reference to the relevant legal provision of the regulatory act, which addresses the specified topic, by indicating the chapter, paragraph and/or page number. If they select NO for any element, it is assumed that they must further elaborate in the "Notes" field. In any case, whether they select YES or NO, Users can provide additional comments in the "Notes" field (as needed), which can help to have more clear understanding on the existing situation with regard to regulation of a particular element.

4.7 "Q6. Please indicate whether there is a need to have legal-regulatory act for this component? "

This question must be addressed only if the answer to Q1 is NO, i.e. if the particular component is not regulated by any legal-normative act.

The purpose of this question is for the Users to provide their assessment on whether there is a need for such regulation by selecting YES or NO, and, in any case, they should also further elaborate by providing additional arguments for either not having such regulation, or describe their vision of the next steps, if such regulation has to be developed (i.e. by whom, when, etc.). This information must be provided in "Component Summary" field.

4.8 "Q.7 Based on the results from Q1 and Q5 please assess the current status of this components regulation by choosing one of the following options:

- This component has sufficient legal-normative regulation, no additional actions needed.
- This component has legal-normative regulation but needs revision and/or further development.
- This component is not regulated by any legal-normative document."

The purpose of this question is to provide short, one sentence summary on the current regulatory status of the particular component, which should be logically based on the information which is provided in the table under Q.5. Users must answer this question by selecting one of the provided options, and the relevant conclusion is then automatically copied into the "Summary Table" under specific color: i.e. green for option 1, yellow for option 2 and red for option 3.

4.9 "Component Summary".

This field must be filled in manually by Users, generally for all components, in order to provide additional information that reflect on the answers to Q.3, Q.5, Q.6 and Q.7.

Users may decide to skip filling in this field only in cases, when, according to their overall assessment, the given component has sufficient regulation which fully reflects on all important elements of people-centred model of TB care (i.e. if they have selected YES to all questions under Q.5 and then selected the first option under Q.7).

5. Reporting on the Results of Regulatory Framework Assessment

5.1 After completion of all component sheets in the Matrix, Users shall compose a country report on the results of regulatory framework assessment on people-centred model of TB care, using the attached Reporting Format as a template.

5.2 The structure of the report is based on four major sections of TB policy and regulation (see p. 2.2 of this Manual). The report should also contain an Executive Summary of the TB regulatory framework in the country, as well as recommendations for amendments and strengthening of the regulatory framework for each section.

5.3 Users should refer (but not be limited) to the information in "Component Summary" field of each component sheet in the Matrix, as well as to the "Notes" section of Q.5 table during writing of the report.

5.4 The “Summary Table” sheet of the Matrix, containing the full list of current TB regulations, shall be attached to the report as its Annex 1.

5.5 Based on the provided recommendations for each section, Users should fill in the action plan template of the reporting format, which shall be attached to the report as its Annex 2.

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