World Health Organization

FOURTH MEETING OF THE MEMBER STATE MECHANISM ON SUBSTANDARD/SPURIOUS/FALSELY-LABELLED FALSIFIED/COUNTERFEIT MEDICAL PRODUCTS
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A proposal for a study on the public health and socioeconomic impact of substandard/spurious/falsely-labelled/falsified/counterfeit (SSFFC) medical products

Economic impact study of falsified and substandard medicines

Paper submitted by the technical group established to conduct the study on the public health and socioeconomic impact of SSFFC medical products

INTRODUCTION

Although the health impact of falsified and substandard medicines is appreciated by all, experts struggle with quantifying the true costs and the socioeconomic impact. According to the Institute of Medicine in the United States of America, it is difficult to measure the public health burden of falsified and substandard drugs, the number of deaths they cause, or the amount of time and money wasted using them.[1] The literature suggests that the scope and scale of the problem differ globally, with the greatest impact experienced in low- and middle-income countries, and that there is a relationship between regulatory stringency and the burden of SSFFC medical products.[2,3,4] Inadequate legislation and weak regulatory and enforcement capacity limit countries' abilities to reduce vulnerabilities in their supply chain. However lack of understanding of the public health and economic costs has frustrated efforts at making the argument that investments in strengthening regulatory systems are a good buy and has prevented countries from understanding and acting on the problem in their own settings.

[1] IOM (Institute of Medicine), 2013. Countering the problem of falsified and substandard drugs. Washington, DC: The National Academies Press.

[2] Rozendaal J. Fake antimalaria drugs in Cambodia. Lancet 2001; 357:890.

[3] Bate R, Coticelli P, Tren R, Attaran A (2008) Antimalarial Drug Quality in the Most Severely Malarious Parts of Africa – A Six Country Study. PLoS ONE 3(5): e2132. doi:10.1371/journal.pone.0002132.

[4] Oxfam briefing paper, 2011. Eye on the Ball: Medicine regulation – not IP enforcement – can best deliver quality medicines. Available from http://www.oxfam.org/sites/www.oxfam.org/files/eye-on-the-ball-medicine-regulation-020211-en.pdf.

Problem statement

There is a need for an economic and health impact study that would make explicit the costs of falsified and substandard medicines to a health system, as well as the benefits of stronger regulatory oversight, in order to advance worthwhile investments in regulatory systems. To be truly useful such a study will need to consider the health and economic costs from a broad societal perspective, consider opportunity cost by estimating the cost for a person of not having safe and quality medicine administered,[1] and consider the possible costs of developing ways of reducing the impact of SSFFC medical products. Pieces of information exist on the various components but none of the relevant studies appear to have put the pieces together. These problems are exacerbated at the country level where many low- and middle-income countries are not in a position to assess the extent, nature and costs of SSFFC medical products in their own settings.

Objectives of the study

The objective of the study is to provide information and quantify the cost and socioeconomic impact of falsified and substandard medicines and establish the potential costs and benefits of strengthening regulatory systems to secure the health products supply chain. A second objective is to suggest a method that countries can use to assess the extent of the problem domestically based on the experience of the first objective. Policy options for addressing any problems identified at the country level are beyond the scope of this study and the remit of the countries concerned.

Potential research aims

1. Estimate the health and economic cost of poor quality and falsified products (measuring direct and indirect costs) using the available published and unpublished literature and databases.[2]

2. Determine the costs of implementing, scaling up and supporting alternative options for strengthening regulatory interventions to reduce the health and economic impacts of SSFFC medical products, with the geographical focus of this work depending on the available data.

3. Assess the possible benefits of alternative options for strengthening regulatory systems.

4. Make recommendations for how countries could seek to try to identify the health and economic costs of SSFFC medical products in their own settings.

Study implementation plan

WHO will hire consultants to develop the analysis based on the published and unpublished literature and various databases that are available to the Organization. WHO will also put together a panel of experts from around the world who will advise on the terms of reference and on the draft report. Two meetings of the panel of experts are envisaged, the first one a virtual meeting to comment

[1] Compared to what would have happened if safe and quality medicines had been received.

[2] In the timeframe of the study, it will not be possible to try to undertake primary data collection. Unpublished literature includes research papers available online and consultancy reports from agencies such as WHO. Data that are not in the public domain will not be sought for this study.

on the terms of reference and possible methods, and the second one a face-to-face meeting to comment on the draft report to facilitate its finalization.

Products expected from the study

1. Information-base of current literature on costs, consequences, and impact of falsified and substandard medicines.

2. Final study report on the health and economic impact of SSFFC medical products and the costs of various options for strengthening regulatory systems.

3. An appendix outlining a possible method for countries to use to assess their own health and economic costs associated with SSFFC medical products.

Potential use and impact of the study

It should provide information and evidence that can be used by WHO and other partners for advocacy and which can be used by countries as the basis of their own policy work to identify ways to strengthen their regulatory systems and secure their supply chain from falsified and substandard products.

Possible constraints

The data on which this study must be based are scattered, heterogeneous, and of varying quality. Accordingly, the final report will show clearly what assumptions were made and the strengths and weaknesses of the data on which the conclusions were reached – if necessary with full details in an appendix.

Proposed timelines

July 2015 to November 2015.

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