Meeting Summary

Counterfeit, Falsified and Substandard Medicines

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SUMMARY

This report summarises the main issues and discussion points raised during the Roundtable on Counterfeit, Falsified and Substandard Medicines hosted by the Centre on Global Health Security at Chatham House on 16 December 2010.

The Roundtable reviewed the current definitions and legal provisions related to counterfeit, falsified and substandard medicines at national and international levels. It examined proposals for revising current definitions in order to facilitate international dialogue and contribute to resolving ongoing disputes over the definitions and how best national governments and international agencies can combat these dangerous medicines.

There was agreement that a framework encompassing the three concepts of counterfeit, falsified and substandard was appropriate and could offer a way forward. Most participants thought the definition of substandard was not problematic – the real issue was whether there was a need to distinguish between counterfeit and falsified medicines; if so, what the precise nature of the distinction was; and what the practical implications of making (or not making) this distinction were.

The suggestion was made that the World Health Organization/International Medical Products Anti-Counterfeiting Taskforce (WHO/IMPACT) definition could be changed to refer to ‘falsified’ rather than ‘counterfeit’ medicines. If that change were made, then the meaning of ‘counterfeit’ medicines would revert to that referred to in the World Trade Organization’s Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) - a wilful form of trademark infringement. For some countries, it was important that WHO should not endorse a definition that could imply WHO involvement in intellectual property (IP) enforcement. A possible solution suggested was to exclude trademark issues from the definition of falsification used by WHO, recognising that these are adequately covered by the TRIPS definition of counterfeiting, and that civil trademark infringement was not relevant.
INTRODUCTION

On 16 December 2010, the Centre on Global Health Security, Chatham House held a Roundtable on Counterfeit, Falsified and Substandard Medicines for about 25 representatives of concerned international organizations, governments, industry, academia and civil society.

This report summarises the main issues and discussion points raised during the Roundtable. The context for the Roundtable was provided by the controversies in the World Health Organization (WHO) and elsewhere that centred on the definition of counterfeit medicines, and the implications for the ways and means of combating them. The purpose of the meeting was to help refine definitions of counterfeit, falsified and substandard medicines and to consider possible ways forward for the international community in addressing the health hazards they pose. In particular, it was intended to contribute constructively to the work of the intergovernmental working group established by the World Health Assembly in May 2010 to consider WHO’s role in the prevention and control of medical products of compromised quality, safety and efficacy, and closely related issues.

Background

Counterfeit, falsified and substandard medicines pose a considerable threat to health security. They can fail to cure, promote antimicrobial resistance or cause injury and death. The threat from them is growing, particularly in poorer countries with weak regulatory mechanisms and poorly monitored distribution networks. Poor patients in developing countries, who usually have to procure medicines with their own resources, are particularly vulnerable. Selling counterfeit medicines can be very profitable, and producers of counterfeits are increasingly sophisticated.

WHO has had a longstanding interest in combating counterfeit, falsified and substandard medicines dating from the 1988 World Health Assembly Resolution 41.16 and culminating in the launch of the International Medical Products Anti-Counterfeiting Taskforce (IMPACT) in 2006.

But the issue of counterfeit medicines has now become extremely controversial. The definition of counterfeit medicines that WHO first developed in 1992, and that IMPACT subsequently revised in 2008, has generated continuing controversy by extending the concept of counterfeiting - which has a specific meaning in relation to IP - to issues concerned with the
quality, safety and efficacy of medicines. Some countries strongly contend that counterfeiting is about the protection of a private right - intellectual property - rather than the protection of public health. They believe that by appearing to prioritise counterfeiting, WHO’s role as a public health agency is compromised and that its principal role should be to combat substandard drugs - of whatever origin - as part of its mandate to protect public health.

Concerns have been raised that confusion over definitions will lead to threats to the legitimate trade in generic drugs. These concerns have been exacerbated by the detention in the European Union in 2008 of generic versions of brand name drugs in transit from India to other developing country markets on the grounds that they were infringing European patents; and by suspicions over the possible impact of the Anti-Counterfeiting Trade Agreement (ACTA) being negotiated between developed countries and some emerging economies to establish higher international standards for IP rights enforcement.

Following intensive discussions at the World Health Assembly in 2010, WHO Member States decided to set up an intergovernmental group to make recommendations by May 2011 on WHO’s role in relation to counterfeit, falsified and substandard medicines.
THE ROUNDTABLE

Introduction
The Roundtable reviewed the current definitions and legal provisions related to counterfeit, falsified and substandard medicines at national and international levels. It examined proposals for revising current definitions in order to facilitate international dialogue and contribute to resolving ongoing disputes over the definitions and how best national governments and international agencies can combat these dangerous medicines. The final session allowed participants to express their views on how to move forward.

International Perspectives
The evolution of WHO’s work and mandate on counterfeit medicines was considered, including the definition adopted by WHO and subsequent modifications agreed under the auspices of IMPACT in 2008. This definition was contrasted with that of ‘counterfeit trademark goods’ in the World Trade Organization’s Agreement on Trade-Related Intellectual Property Rights (TRIPS). Whereas TRIPS restricts counterfeiting to goods bearing a trademark that is (essentially) identical to a validly registered trademark, the WHO/IMPACT definition expands this to a false representation in relation to identity or source.

National and Regional Perspectives
Perspectives were presented from the USA, Europe, India and the Asia-Pacific region. There was a wide variety of national and regional interpretations of counterfeit medicines. These included definitions along the lines of TRIPS, but some countries broadened the usage to encompass IP rights other than trademarks. Other countries drew on the WHO/IMPACT definition but many included characteristics not included in that definition. In some countries and regions, ‘falsified’ medicines were given a legal meaning relating only to public health, completely separate from IP rights. In the case of the Council of Europe MEDICRIME Convention, ‘counterfeit medicines’ were defined along the lines of the WHO/IMPACT definition, but explicitly excluded IP rights.
Definitions

The Roundtable did not succeed in producing revised definitions on which all parties could agree. But there was a helpful discussion of principles and objectives, and agreement that the framework encompassing three concepts of counterfeit, falsified and substandard was appropriate and could offer a way forward. Most participants thought the definition of substandard was not problematic – the real issue was whether there was a need to distinguish between counterfeit and falsified medicines; if so, what the precise nature of the distinction was; and what the practical implications of making (or not making) this distinction were.

The suggestion was made that the WHO/IMPACT definition could be changed to refer to ‘falsified’ rather than ‘counterfeit’. If that change were made, then the meaning of ‘counterfeit’ medicines would revert to that referred to in TRIPS. This formulation would have the principal merit of resolving (for the most part) the confusion arising from the two different prevalent definitions of counterfeit. Secondly, it would clarify that the interest of WHO/IMPACT was not in counterfeit goods per se, but in all kinds of falsified medicines, whether or not they infringed trademarks (or indeed other IP rights). On the other hand, to the extent that counterfeiting is a subset of falsification, it does not draw a clear dividing line between the two concepts. For some countries it was important that WHO should not endorse a definition that could imply WHO involvement in IP enforcement. A possible solution suggested was to exclude trademark issues from the definition of falsification used by WHO, recognising that these are adequately covered by the TRIPS definition of counterfeiting, and that civil trademark infringement was not relevant.