

## **A Call to Action: Furthering the fight against falsified and substandard medical products**

Falsified and substandard medical products<sup>1</sup> (including vaccines, medical devices and veterinary products) – products that are ‘fake’ or of poor quality – are an increasing global scourge that threaten life, health and security in significant ways. Patients receiving these products not only get ineffective treatment but are also often exposed to serious harm. The toll from these products may be as high as a million lives lost per year. In addition, their use increases the risk of drug resistant infections, and expenditure on ineffective or harmful products depletes much-needed healthcare resources. This serious and growing problem has been exacerbated by the increasing complexity of global supply chains, as well as by the inappropriate sale of medical products on the internet or in open markets. Nonetheless, efforts to tackle this issue have been woefully inadequate, reflecting in part the magnitude of the problem but also a lack of sustained political will and commitment to act.

The Inter Academy Partnership (IAP) deplores this situation and urges political decision-makers at all levels, in concert with regional and international organizations, to work with medical product regulatory authorities, national and international law enforcement agencies, manufacturers, importers, distributors, health professionals and patients to solve this urgent issue.

### **Introduction**

Falsified and substandard medical products are a global public health threat. Traffic in these products is constantly growing, impacting patients particularly in low-income countries where resources to help keep such products off the market are limited. These problems have also reached worrying levels in many high-income countries, including in Europe and the USA. Any medical product can be falsified or made in a substandard manner, including both innovator products and generics, whatever their price. Internet and open market sales that bypass national quality control systems and/or regulated channels are worsening the situation<sup>i,ii</sup>.

Such products harm patients by denying them the benefit of a safe and effective treatment. In many cases, the wrong active ingredient, an incorrect amount of the active ingredient, or no active ingredient at all can be found. As such they can result in serious therapeutic failures, as well as the development of drug resistance, particularly in the fields of antibiotics, anti-malaria or anti-viral products. They can also be dangerous per se, as they may include toxic compounds<sup>iii</sup>.

Despite these harmful effects it has been difficult to limit the traffic for many reasons including:

- *Detection*: Current manufacturing and printing techniques allow the production of very closely copied, falsified packaging that is difficult for even the trained eye to detect. In

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<sup>1</sup> While substandard and falsified medical products are somewhat different in nature and covered by different regulations, the public health consequences of accessibility to both types of product are fundamentally similar for the patient. This IAP Statement, therefore, applies to both substandard and falsified medical products.

addition, poor quality manufacturing leading to substandard products requires rigorous oversight while resources for inspection and compliance are often lacking;

- *Discovery*: At present, the methods for discovery are often medical, such as finding that a treatment is ineffective or discovering unusual side effects. The cause of these effects may not be easy to identify, especially in countries with limited medical and laboratory resources. Routine surveillance or insider reporting are also factors in discovery. However, systems for detection and reporting are often inadequate;
- *Danger of internet or open market sales*: On the internet and on the open market, medical products lose the protection of the usual lawful professional distribution chain. Under these circumstances it is very difficult for patients, even if they are aware of the risks, to ensure they are acquiring an appropriate, safe, genuine and effective drug (i.e. to determine which products are legitimate and which are not).

The current means to combat this extensive problem are limited:

- The legal framework is not fit-for-purpose in many countries; internet and other cross-border sales blur jurisdictions and the possibility of legal sanctions;
- The various responsible bodies are often fragmented at national and international levels;
- Detection techniques exist but they are still not adequately developed or effectively implemented. Additionally, approaches differ from one country/region to another;
- The pharmaceutical supply chain may lack full integrity due to limited regulatory oversight and/or capacity, or it may be weakened by deregulation based on economic or trade considerations rather than public health criteria. In addition, in many countries, especially low-income countries, it is difficult to control all commercial activities effectively, in particular those of wholesalers and importers.

Not all actors are committed to preventing the sale of falsified and substandard products on their markets. In particular there is often:

- Lack of political engagement at the national level, with lack of support to domestic agencies as well as a lack of national policies to assure access to affordable, quality medical products, which can prompt consumers to seek alternative sources of medications;
- Inadequate oversight and stewardship of pharmaceutical products and practices;
- Lack of consistent and effective legal and judicial frameworks;
- Limited capacity in many countries of certified laboratories able to detect fraudulent products in the supply chain, most particularly of concern in low income countries;
- Health professionals (physicians and pharmacists) are not always aware of risks and are not adequately warned in a timely fashion of the presence of falsified and substandard products on their markets, some of which may be very sophisticated fakes. They are sometimes isolated and not well-trained in this regard. As a result, it is difficult to engage them to confront this scourge;
- In general, the public is unaware of, or not well enough informed about, this problem, particularly the risks of buying these kinds of products on the internet, at open air markets, or otherwise outside of the regular, lawful, quality-assured pharmaceutical supply chain. In these extra-lawful environments, it is nearly impossible for consumers to differentiate legitimate from illegitimate products.

Falsified and substandard medicines are an international issue that threatens people around the world, involving numerous different actors and a diverse set of stakeholders. Solutions to this urgent and complex problem cannot be considered in an isolated way. A shared commitment to the effective coordination and the engagement and mobilization of all players is necessary if we are to succeed.

## Background

Falsified and substandard medicines have been a long-standing concern, yet no comprehensive, well-resourced and sustained international campaign has been organized and waged, despite some limited national and international initiatives. For a long time, one of the impediments to comprehensive international action was a tension between public health considerations and intellectual property debates. For example, the word 'counterfeit' was generally considered to refer to products that infringe on the patents in a market where such patents are in force. As several countries perceived this as potentially blocking cheaper legitimate generic copies of these products, they were unable to support early drafts of resolutions and actions proposed by the World Health Organization (WHO). To try to clarify the situation, it was decided to use the acronym SSFFC (Substandard, Spurious, Falsely labelled, Falsified, Counterfeit)<sup>iv</sup>. This was an effort to try to differentiate the public health problem of falsified and substandard products from the intellectual property issues. More recently, in an attempt to further clarify the public health problem caused by these products, the WHO Member States Mechanism proposed the terms 'substandard and falsified medicines' to designate the products that are the focus of these activities. This terminology was adopted by the May 2017 World Health Assembly (WHA). The definition adopted for 'falsified products' is: "Medical products that deliberately/fraudulently misrepresent their identity, composition or source". The agreed definition for 'substandard products' is: "Authorized medical products that fail to meet either their quality standards or their specifications or both". These definitions are clear progress in clarifying the meaning of the terms, as well as the focus of efforts to confront this public health challenge<sup>v</sup>.

In addressing the problem of falsified and substandard medical products two distinct, though related, avenues of concern arise:

- Penetration of such medical products into the legal, regulated supply chain;
- Direct to the public licit or illicit marketing of medical products (e.g. via the internet or in open markets).

Given the seriousness of the issue, it is troubling that there are not better sources of data about the magnitude and scope of the problem. New efforts are underway to address this shortcoming. At present, however, it is difficult to give precise numbers, but it appears that in many low-income countries a large proportion of the medical products available are falsified or substandard. Estimates of 20-30% in some African and Asian countries seem realistic<sup>vi</sup>. Some estimates for particular products are even higher, including an extremely worrisome 30-50% for anti-malarial drugs in south-east Asia<sup>vii</sup>. Of note, some 50% of all reports of substandard and falsified medicines received by the WHO Global Alert system are from sub-Saharan Africa, and 80% of these are for essential medicines like antimalarials and antibiotics<sup>viii</sup>.

High-income countries are also impacted. For example, in the United States, several instances of falsified drugs are detected each year. The US Food and Drug Administration (FDA) has launched an alert system, publishing these cases to warn the public<sup>ix</sup>. In Europe, a link has been established between the deregulation of the distribution chain and the number of falsifications detected<sup>x</sup>. Some 50% of the products proposed for sale on the internet are also believed to be falsified<sup>xi</sup>.

There have been a range of efforts to combat falsified and substandard medical products, many organized at a national level, as well as a few specific international operations such as Jacques Chirac's 'Call of Cotonou'<sup>xii</sup>. The International Medical Products Anti-Counterfeiting Taskforce (IMPACT) represented an earlier more international effort launched by WHO (2006-2010), but it was put on hold due to conflicts among Member States based on disagreements over counterfeit drugs

definition, the enforcement of patents and the public health impacts described above. The recent Member State mechanism framework and activities offer new opportunities for collaboration and action, including the 2017 World Health Assembly resolutions on this topic<sup>xiii</sup>.

It is also necessary to recognize the efforts that have been made internationally to address the problem. At the inter-governmental level these include the important Council of Europe's (CoE) MEDICRIME Convention<sup>xiv</sup>, open also to countries that are not members of the CoE; the European Union's Falsified Medicines Directive 2011/62/EU which has introduced regulatory constraints to all stakeholders; as well as the successful international cooperation which has been achieved in Operation Pangea initiatives against online sales of falsified and substandard medicines. Importantly, the WHO has significantly increased its surveillance, monitoring and programmes in this area. Despite very limited resources, WHO currently hosts a database recording the different cases reported and working with over 150 Member States to develop better means of detection, reporting and collaboration to improve identification of such products and their removal from national and international commerce.

### **Previous work by academies**

In 2011, the US Institute of Medicine (now called the National Academy of Medicine) undertook a major study of this issue, assembling a diverse, international expert committee. Their report and recommendations were released in February 2013 in a document entitled 'Countering the Problem of Falsified and Substandard Drugs'<sup>xv</sup>.

The French Academy of Medicine, in collaboration with the French Academy of Pharmacy and the Veterinary Academy of France, undertook an effort in 2015 to prepare a report describing the facts, analysing the different aspects and factors impacting the problem, and proposing some recommended actions. This report was presented at the Academy of Medicine's plenary session in December 2015<sup>xvi</sup> with a public manifesto signed by the three French academies as well as by the presidents of the three health professional chambers<sup>xvi</sup>.

These important efforts have underscored the fact that falsified and substandard drugs represent an international problem requiring international cooperation. They also underscore the urgency of meaningful and sustainable action.

### **Recommendations from IAP**

IAP for Health seeks to draw attention to the necessary fight against the global trafficking of falsified and substandard medical products, and supports the call for a comprehensive, well-resourced, international effort to address this devastating problem. IAP for Health member academies consist of national and international leaders of the academic and scientific communities with important access to policy makers, key stakeholders and the public. They must use their unique position to actively promote this fight around the world to benefit public health and foster better healthcare for all.

IAP for Health and its member academies, recognizing the increasing trafficking of these products throughout the world, and the almost total impunity of the perpetrators, despite the risk to the life and health of patients, denounce the gravity of these criminal practices. They call for the launch at an international level of a strong, comprehensive, well-resourced policy and programme of prevention in the fight against this scourge. This must include the development and implementation of informed policies; the adequate funding of regulatory oversight systems; strengthened, coordinated

enforcement mechanisms; the development and utilization of easy to use and affordable detection equipment; and the education of the public and healthcare providers.

IAP recommends that the terms 'falsified' and 'substandard' medicines and their definitions as recently adopted by WHO and the World Health Assembly be used worldwide, and that this issue be entirely separated from discussions about intellectual property rights.

IAP underlines that the right of people to health is unalienable. Manufacturing, carrying, stocking and selling falsified and substandard medical products, including drugs, vaccines, medical devices, and other medical products are crimes. Due to their severe consequences on public health and individual healthcare, these crimes must be prosecuted and punished to the fullest extent possible.

Given that this activity affects every country in the world, IAP emphasizes that governments, regulatory authorities and industry must oversee and regulate the supply chain effectively in order that the security and the continuity of the supplies of medical products are guaranteed, especially in countries most burdened by the problem of falsified and substandard drugs. This can be achieved through robust oversight of good manufacturing processes, the use of comprehensive and cost-effective technologies, wholesaling transparency, and traceability of products from manufacturing to market, including the financial flows. This also requires a renewed attention to quality control and assuring that regulatory authorities and law enforcement and judicial authorities are adequately resourced, trained and empowered.

IAP strongly affirms the importance of warning the public about the risk of buying prescription medicines over the internet and of advising online purchase only through certified internet pharmacies. In this regard, groups such as the Alliance for Safe Online Pharmacies (ASOP)<sup>xvii</sup> represent valuable assets. In many countries, similar efforts must be undertaken to educate and warn the public about the risks of purchases in open marketplaces.

IAP decries the delays and the insufficient resources invested in this fight. Specific one-off operations, even if locally efficacious, are not sufficient. It is necessary that global intergovernmental and intersectoral actions are agreed on, coordinated and sustained.

IAP underscores the fact that the prevention of this threat requires improved access to legitimate, quality medical products, including equitable pricing policies and better healthcare coverage.

IAP recommends strong consideration of a substantive, comprehensive and well-resourced policy and programme to address this scourge as a priority action of national authorities and international organizations in charge of public health, including the extension of the MEDICRIME Convention.

Lastly, IAP agrees that WHO is uniquely situated, through its membership and global remit, to provide leadership and coordination to combat this pressing problem. We therefore call on our national governments to support WHO in this effort and to hold them accountable for progress. We request that WHO sponsor a resolution at the next World Health Assembly that will call upon the WHO to coordinate and implement a major, comprehensive and sustained effort in this regard. Further, we call upon our national governments to assure that WHO has adequate financial and technical resources specifically to implement any such World Health Assembly resolution.

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The fight against falsified and substandard medicines is a global threat that must be addressed through global cooperation and collaboration. All stakeholders – at international, regional and national levels – should join forces to implement these recommendations to help improve public health worldwide.

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