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Fluid Fakes, Contested Counterfeits: The World Health Organisation's Engagement with Fake Drugs, 1948–2017

Abstract

In recent decades, the scientific and medical literature has routinely argued that 'fake' drugs present a pressing threat to global health. However, this article steps back from the chorus surrounding fake drugs, to ask what wider issues have been at stake in efforts to control and combat them over the last seventy years. Focusing on the World Health Organisation (WHO), it presents a genealogy of its engagement with fake drugs as part of its work on pharmaceutical quality, from 1948 until 2017 when the latest nomenclature of 'substandard and falsified medical products' was adopted. The seizure of shipments of Indian generic drugs by EU customs authorities from 2008, on the basis that they infringed local patents and hence were 'counterfeit', underlines that the specific terms used to describe fake drugs in global health are not neutral technical objects, but highly-charged political devices that serve the interests of particular actors.

Keywords: World Health Organisation, global health, pharmaceuticals, quality, substandard, counterfeit, falsified, fake

Introduction

This article presents a history of the World Health Organisation's engagement with fake drugs, as part of its work in relation to medicines. Drawing upon a survey of published and grey literature, including correspondence from the World Health Organisation (WHO) archives, it explores the shifting terminology around fake drugs in the WHO's technical vocabulary, and the political and economic conditions that influenced the emergence of these terms.

The WHO was established in 1948 as the specialised agency of the United Nations dedicated to international public health (Cueto, Brown, and Fee 2019).

Headquartered in Geneva, it carries out several important functions in relation to medicines. Through its expert committees, the WHO develops international norms and standards, for example quality specifications and test methods for pharmaceuticals (as laid down in the *International Pharmacopeia*). It provides technical assistance to member states, such as helping them to develop national medicines policies. It promotes access to medicines and supports the procurement of drugs in low-income countries by 'prequalifying' drugs that meet recognised quality standards. It also plays an important role in pharmacovigilance, through its Programme for International Drug Monitoring. The WHO is not an international regulatory agency, however, and it has no power to enforce its resolutions and decisions on member states. The WHO's programmes are funded by assessed contributions from member states (based on their wealth and population), voluntary contributions, and contributions from private donors. In recent decades, the WHO's authority has been questioned, as private donors, global partnerships, and international financial institutions have come to dominate the global health agenda

(Brown, Cueto, and Fee 2006; Packard 2016). Nevertheless, the WHO continues to play a strategic role in coordinating international action on important health issues. The WHO's decision-making body, the World Health Assembly (WHA), meets annually and is composed of representatives of all member states. It acts as an important international forum for debate and discussion about medicines and other health topics.

In recent decades, few issues in the WHO's work on medicines have proved as divisive as the use of specific terms to define drugs which either fail to meet recognised standards of quality or are deliberately falsified in relation to their identity, composition, or source (herewith, captured under the heading 'fake') (WHO 2017). The term 'counterfeit', especially, attracted considerable opposition from access-to-medicine advocates, generic drugs manufacturers, and governments of various low- and medium-income countries (LMICs) including India and Brazil. They argued that the use of this term conflated the protection of public health with intellectual property rights. Thus, the term 'counterfeit' could be applied inappropriately to legitimate generic drugs, which have been vital to securing access to medicines in many countries (Gopakumar and Shashikant 2010). These fears were not unfounded: since 2008, several shipments of Indian-made generic drugs have been seized in transit through the European Union, on the basis that they infringed local patents (Zarocostas 2010; Mercurio 2012).

This controversy over counterfeit drugs within the WHO highlights that the terms used to define fake drugs are not unproblematic or self-evident, as much of the medical and scientific literature on fake drugs would seem to suggest. Rather, they

are politicised objects which are subject to negotiation and contestation, and which can serve the interests of various actors. While governments and national drug regulatory agencies (NDRAs) ultimately enshrine particular terms in legislation and regulatory practices, this international terminology debate has animated how fake drugs have been problematised and approached globally. In this article, I examine the wider issues at stake in efforts to define fake drugs in the WHO, contextualising how these terms emerged in response to changing historical conditions and political interests, and in response to changes within the WHO itself.

To achieve this aim, I recount four ‘chapters’ in the WHO’s engagement with fake drugs, from 1948 to 2017 (when the WHO adopted its latest terminology of ‘substandard and falsified medical products’). Each chapter focuses on a specific term (or set of terms), which represent a particular configuration of debates around drugs in the WHO at different periods of its history. These terms are: ‘quality,’ ‘substandard,’ ‘counterfeit,’ and for reasons that will become clear, the rather unwieldy expression ‘substandard/spurious/falsely labelled/falsified/counterfeit’ (SSFFC). As configurations of debates around drugs evolved in the WHO, important aspects of the problem of fake drugs were defined and reconceptualised. In each chapter, I highlight the relationship between the dominant discourse around drugs in the WHO, and the approaches to fake or suspect drugs this discourse supported. I also analyse associated claims around fake drugs, showing how issues of drug quality and ‘fakeness’ were mobilised by actors at different times and locations.

The result is a genealogy of the WHO’s technical vocabulary around fake drugs. However, its periodisation is uneven, because the international lexicon around fake

drugs has been so complex. Some chapters evince scenarios of accumulation, when specific terms (such as 'substandard') gained salience in WHO discourse and remained in use over time. Others evince scenarios of succession, since some debated terms (such as 'counterfeit') were stricken from the WHO's lexicon. Still others represent scenarios of continuity, since some terms (such as 'quality') persisted over time. The following narrative is therefore chronological, but complicated by the specific trajectories and destinies of the terms under analysis. Each chapter, however, provides a basis for understanding facets of the fake drugs phenomenon, as well as subsequent developments.¹

What follows, therefore, is not simply a history of WHO technical frameworks around fake drugs. Instead, it presents an analysis of the wider conditions that shaped considerations of the fake. By treating the terms used to define fake drugs in WHO as a starting point for analysis, this article, like others in this special issue, steps back from the well-rehearsed chorus decrying fake drugs in global health (e.g., Bate 2012; The Lancet 2012; IMPACT 2006, 2011). Of course, it is important to recognise that drugs which fail to meet required quality standards, or which have been falsified, *do* present significant dangers to public health, and there are many examples of such drugs in the medical-scientific literature. However, by unveiling the fraught and interested nature of the terms used to define fake drugs in global health, this article denaturalises such terms and asks wider questions about them.

¹ It is also important to note that the terms under analysis were not the only ones in circulation. Over this long period, fake drugs were not referred to consistently. A variety of terms were favoured by different member states and non-governmental actors (such as 'spurious', 'mislabelled', or 'misbranded'), each illuminating different aspects of this complex phenomenon. The terms analysed have been chosen because they help to deconstruct the configurations of debates that shaped discussion of fake drugs in the WHO at different moments in time.

This continues an important theme of inquiry in the anthropology of pharmaceuticals. The idea that medicines are ‘fluid’ objects whose contested meanings, descriptions, and labelling influence their social effects is not a novel insight. As Hardon and Sanabria (2017, 127) emphasise, ‘there is no pure (pharmaceutical) object that precedes its socialization and interpretation’. Anthropologists have stressed the importance of culture in shaping the production, distribution, and consumption of drugs. They have argued that pharmaceuticals have ‘social lives’ and act as social agents (Whyte, Geest, and Hardon 2002). Scholars have also interrogated the wider concept of ‘fakeness’, stressing the importance of performativity (such as exposure) in objectifying fakes and convincing others of their existence and effects (Copeman and da Col 2018). Despite these observations, however, few works have sought to unpack the terminologies underpinning global action on fake drugs, perhaps because the issue has been typically seen as self-evident (though see Quet 2018; Gopakumar and Shashikant 2010). One notable exception is Emilie Cloatre (2016, 106), who has highlighted the role played by ambiguous legal-technical definitions in shaping attitudes towards fake drugs, or ‘how uncertain legalities translate into uncertain sociality of certain types of medicines’. For example, in Ghana, concerns about counterfeit drugs allow legitimate generics to fall under suspicion and influence how such drugs are bought and consumed (people may choose a UK-produced generic over a cheaper Indian one, for instance, on the basis that the former is more trusted). What is special about fake drugs, as Cloatre’s work shows, is the sheer extent of their slipperiness—how they can fuse many different concerns. The problem lies not only in differentiating ‘real’ from ‘fake’ drugs but, potentially, legitimate from illegitimate, brand from imitation, originator from copy, and effective

from non-effective. The following genealogy seeks to capture and unravel this intricacy.

‘Quality’: The conditions of possibility of fake drugs (1948 to present)

Why begin a genealogy of the WHO’s engagement with fake drugs with a discussion of pharmaceutical quality? Claims about the legitimacy of various objects, including their ‘fakeness’, are often supported by reference to *standards*: norms, benchmarks, comparators, or descriptors against which the objects in question can be assessed and categorised. Technical standards of quality have long been an important arbiter of pharmaceuticals’ authenticity, legitimacy, and suitability for purpose. Defined by a broad array of attributes, including identity, purity, potency, and uniformity (among others), and demonstrated through measures such as inspection, the quality of drugs is the primordial concern from which pharmaceutical regulation in most countries stemmed.

Broadly conceived, concerns about drug quality have existed for centuries. A desire to achieve consistency in the manufacture and effects of drugs, and to tease out those that were suspect, underpinned the development of formal specifications for drugs, as laid down in pharmacopoeias. Fears about adulteration, mislabelling, and misrepresentation also informed the national control of medicines. In sixteenth-century London, for instance, the College of Physicians was empowered to appoint inspectors to check the quality of medicines and to destroy wares that were ‘defective’ or ‘corrupted’ (a tradition that continues with the mass burning of suspected fakes by NDRAs in the twenty-first century) (Griffin 2004). Concerns about the purity of food and drugs and the importation of substandard medicines

from abroad informed the Pure Food and Drugs Act in the United States in 1906, while the Indian Drug Act of 1940 referred to mislabelled, spurious, and adulterated substances, among other things.

As the international trade in pharmaceuticals expanded over the twentieth century, the need for agreed international standards of pharmaceutical quality became increasingly apparent. The therapeutic revolution, with new chemical substances launched onto the global market every year, also compelled greater international cooperation. Hence, a concern with pharmaceutical quality existed in the WHO from its establishment (WHO 1958, 2003). The WHO's constitution, signed in 1946, empowered it to develop and disseminate standards with respect to pharmaceuticals, biologicals, and other products (WHO 1946). It also authorised the World Health Assembly (WHA) to adopt regulations concerning the safety, purity, and potency of pharmaceuticals. Despite these powers, the WHO refrained from making regulations. Instead, it concentrated on the *International Pharmacopoeia*, a set of detailed specifications regarding the identity, composition, posology, and analysis of drugs, used as a basis for the development of national pharmacopoeias and quality standards. In addition, the WHO developed the list of International Non-Proprietary Names for Pharmaceutical Preparations (INN), acknowledging that the proliferation of brand names for drugs led to confusion for regulators, prescribers, and patients (WHO 1958). In the febrile political climate of the Cold War, when UN agencies were viewed with suspicion by the United States government and there was hostility towards supranational authority (Cueto, Brown, and Fee 2019), these standard-setting activities were preferable to regulation or direct intervention into sensitive issues of national jurisdiction, such as pharmaceutical markets.

Accordingly, in its first decades the WHO continued the internationalist tradition of developing technical norms and standards—thereby supporting pharmaceutical trade—rather than directly regulating the quality, safety, and efficacy of drugs. A focus on fake drugs, therefore, was largely absent from international discourse, submerged beneath these more general discussions about drug specifications and naming. It was at the national level where concerns about fake drugs surfaced. Nevertheless, the discourse of pharmaceutical quality established a technical language in which claims of fakeness could engage public health. This created the conditions of possibility for discussion of fake drugs at an international level.

‘Substandard’: Drug safety and quality control in the era of decolonisation (1960s to present)

The technical language of quality, of course, remains central to WHO discussions about pharmaceuticals in the present day. Importantly, however, this technical framing of pharmaceuticals served as the bedrock for further issues and problems around drugs to be articulated at an international level. This includes discussion of fake drugs.

Several issues achieved prominence in the WHO in the 1960s, as the consequences of the therapeutic revolution for international health continued to reverberate and as the makeup of the WHA changed. Notably, the thalidomide scandal in the early 1960s prompted the WHO (as well as governments and NDRA around the world) to focus more directly on the quality control, safety, and efficacy of drugs. For example,

in 1963, a WHO resolution established an international monitoring scheme for adverse drug reactions (WHO 1963b).

More broadly, the 1960s was a decade of transition for the WHO, as the process of decolonisation unfolded. Newly independent nations joined the UN, prompting a reorientation of political relations between global North and South (Chorev 2012). This relationship was fraught owing to intensified Cold War anxieties (the Soviet Union re-joined WHO in 1956) and the appearance of a new bloc of independent nations that the West feared could fall under Soviet influence (Cueto, Brown, and Fee 2019). However, this relationship informed the rhetoric of economic development promulgated during this period, as well as other WHO programmes, such as the Global Malaria Eradication Programme (Packard 1997).

In relation to drugs, decolonisation presented opportunities for newly independent nations as well as pharmaceutical manufacturers in the global North. For newly independent nations, decolonisation encouraged further the local production of pharmaceuticals and the establishment of national systems of drug regulation. For pharmaceutical companies in the global North, on the other hand, decolonisation offered the prospect of new overseas markets. It encouraged them to export a growing number of products, many of dubious quality (Peterson 2014). Buoyed by aggressive advertising, the number of drugs available in the markets of LMICs grew rapidly. At the same time, however, many basic drugs remained unaffordable and inaccessible to the poorest in society (WHO 1985a; Mamdani 1992).

These geopolitical and commercial considerations informed the debate around 'substandard' drugs that intensified in the 1960s (WHO 1963c, 1964). Substandard drugs—that is, those that fail to meet recognised standards of quality—had arguably been an implicit feature of pharmaceutical regulation in countries ever since the first national pharmacopoeias were established. However, there was an international outpouring of concern about these drugs in the 1960s, partly due to the expansion of international pharmaceutical trade and partly because the thalidomide tragedy had sensitised the international community to issues of drug quality and safety. In this context, developing countries, which imported most of their drugs, demanded that the quality of the drugs they imported conform to the same standards as those consumed in the country of export. Delegations at the WHA raised alarm about how pharmaceutical companies based in the global North were deliberately exporting poor quality, even dangerous products (in many cases, those drugs were not authorised for sale in their countries of manufacture, were expired, or had even been withdrawn). As one Nigerian delegate to the WHA remarked: 'concern has lately been expressed that substandard drugs are being dumped into the drug markets of the new countries, where clinical test facilities either do not exist at all, or are grossly inadequate' (WHO 1963a, 117).

Aqueous metaphors were commonplace, capturing a prevailing mood of anxiety about lack of control. A USSR delegate spoke of 'the defencelessness of the population, especially in the developing countries, against the *flood* of preparations, many of them of inferior quality, released on the market' (WHO 1967a, 279, emphasis added). A delegate for Cyprus argued that his 'country's market had been *flooded* with an enormous mass of such preparations, many of them of doubtful

standard' (WHO 1967a, 283, emphasis added). A Romanian delegate complained 'the market was constantly *inundated* with new drugs' (WHO 1967a, 286, emphasis added). Countries with quality control laboratories reported the large-scale distribution of substandard drugs, foreshadowing later claims about the distribution of fakes. For example, in Sudan, 20–40% of imported drugs every year were found to be 'sub-standard or unfit for medical use' (WHO 1968a, 379), while in Czechoslovakia, 13% of tested samples failed to meet specifications (WHO 1970, 366).

Today, substandard drugs form part of the wider landscape of fake drugs, often confused or conflated with 'falsified' medicines. The fact that substandard drugs are reported alongside falsified drugs in the WHO's post-2013 Global Surveillance and Monitoring System (see below) testifies to how the two categories cannot be easily disentangled. Substandard drugs may be produced accidentally, for instance if equipment has deteriorated, or they may be produced deliberately. What is striking about the discourse around substandard drugs in the 1960s and 1970s is the extent to which poor quality but ostensibly legitimate drugs were spoken about alongside those that were more obviously illicit. For example, the Nigerian delegation remarked that:

there were serious fraudulent practices on the part of importing commercial firms that had led to loss of life; physicians sometimes discovered at the cost of a life that a particular brand of drug was useless. Malpractices ranged from a simple dilution or misstatement of the strength of a preparation to downright *fakes*—for example, the sale of chalk tablets to resemble sulfonamide tablets. (WHO 1967a, 283, emphasis added)

Claims about the dumping of substandard drugs often assumed a moralistic tone, one which articulated wider concerns about North–South power imbalances. Poor-quality drugs were deemed variously to be a moral failure of manufacturers, commercial importers, or governments in developed countries that did not set quality standards for exported drugs. The problem also brought into question the role of the WHO. As an Executive Board member for Trinidad and Tobago remarked: ‘To hear of the “double standard” used by some manufacturers was very distressing. ... Countries producing drugs should be responsible for the standards of drugs they exported. It was a moral obligation not to capitalize on the deficiencies of others’ (WHO 1967a, 281).

In the 1960s and 1970s, substandard drugs were therefore cast in two complementary lights. On the one hand, they were conceptualised as a technical issue of quality control, a framing that brought into focus the roles of NDRAs and quality-control laboratories. On the other hand, substandard drugs were framed as part of a wider moral economy, invoking the responsibilities of manufacturers, wholesalers, importers, governments, and even the WHO.

Taming the tide

Ensuring the quality of drugs in international commerce presented many difficulties, as WHO’s second Director-General (1953–1973), Marcolino Candau, recognised. For instance, there was the increasing complexity of pharmaceutical trade. A preparation made in one country might contain active ingredients or excipients produced in another country, whose quality-control mechanisms were unknown or

non-existent. Another issue was poor regulatory capacity in developing countries. Some countries possessed quality-control laboratories, but only tested drugs at the time of manufacture, not after they were marketed; some countries had drug quality regulations but failed to enforce them; others lacked legal requirements for drug quality altogether. For Candau, the ideal solution was for each country to establish a quality-control laboratory. However, this was not easy, considering developing countries' finances and lack of trained personnel (WHO 1964).

Developing countries, cast as the victims of this global trade, were exempt from the moral exhortations described above, but were still encouraged to act, for example by cooperating with neighbours to establish regional quality-control laboratories. By the end of the decade, three other courses of action opened to the WHO. The *International Pharmacopeia* was revised with quality control in mind, incorporating monographs for analytical methods such as non-aqueous titration (WHO 1967c, 1968b). The twentieth WHA in 1967 authorised Candau to devise principles of quality control to be implemented as part of 'good manufacturing practice' (GMP) (WHO 1967b). These guidelines, approved in 1969, laid out the general considerations of GMP, relating to such factors as premises, personnel, equipment, and packaging (WHO 1969).

The WHO's third course of action was developing a voluntary scheme to certify the quality of pharmaceuticals moving in international commerce. The WHO developed model certificates to be adapted by NDRAs, which would assure importers that products had received marketing authorisation and that the manufacturer followed GMP. By 1977, 25 countries were participating, although uptake was lower among

countries of the global South (WHO 1985c, 2008). A review of the scheme in 1985 argued that it was 'not functioning effectively in all countries', and that 'reports of the alleged infiltration of counterfeit drugs, commonly labelled as antibiotics, into some developing countries, underscores the need for substantial improvement in current standards of control' (WHO 1985c). Since the certification scheme existed on paper only, it depended greatly upon trust and the regulatory capacity to implement the scheme.

Rational drug use

By the late 1960s, several countries were taking more radical steps to regulate their pharmaceutical markets. Some, like Sri Lanka, restricted drug purchasing to lists of essential drugs deemed most beneficial to health. These lists usually applied to public sector institutions, such as state hospitals, but were occasionally extended to the private sector (Mamdani 1992). Others, such as Mozambique, centralised drug procurement, purchasing them in bulk through state agencies. Nationalisation was another, more drastic option, as seen in Egypt. Local production was touted as a solution to the problems of the pharmaceutical market, with UN agencies such as the United Nations Industrial Development Organisation (UNIDO) actively assisting countries to establish their own industries. A further strategy was the promotion of generic drugs, as in Pakistan from 1973 (Mamdani 1992).

Developing countries' efforts to restructure and take ownership of their pharmaceutical markets was part of a wider movement, following decolonisation, to reorient their relationship with the global North. The 1974 UN Declaration on the Establishment of a New International Economic Order called for a readjustment in

international relations more broadly, grounded in respect for national sovereignty, fairer terms of trade, and access to the 'achievements of modern science and technology' (United Nations 1974; see also Mamdani 1992; Chorev 2012). The WHO's response was to refine the concept of essential drugs. In 1977, the WHO convened the Expert Committee on the Selection of Essential Drugs, which compiled a list of 220 generic drugs and vaccines deemed 'of the utmost importance and hence basic, indispensable, and necessary for the health needs of the population' (WHO 1977, 9). This was followed in 1981 by the establishment of the Action Programme on Essential Drugs, through which the WHO assisted countries to formulate national drug policies, and later, to directly procure essential drugs (Walt and Harnmeijer 1992). The WHO's promotion of essential drugs proved controversial, with the transnational pharmaceutical industry fearing that the WHO was restricting its marketing. The WHO's support for a code for the marketing of breast milk substitutes in 1981 only increased antagonism between the WHO and industry (Mamdani 1992).

By the mid-1980s, the WHO began to pay attention not only to the availability of essential drugs, but also to the efficiency of the wider field of drug production, supply, and consumption, or what has been termed the 'rational use of drugs'. In 1985, the WHO organised a Conference of Experts on the Rational Use of Drugs in Nairobi, Kenya. It was at this conference that concerns about counterfeit drugs initially surfaced, identified by a peer review group as one of many issues requiring attention (WHO 1985b).

‘Counterfeit’: Global health, drug security, and a new global dilemma (1980s to 2017)

The story of ‘counterfeit’ is connected to wider changes in the politics of international health. The WHO’s authority over international health came into question in the 1980s, as international donors such as the World Bank, nongovernmental organisations (NGOs), and bilateral aid arrangements increasingly dictated health lending priorities. The proliferation of international actors in the field of health, amid growing awareness of the interconnectedness of environments, populations, and economies in relation to health and disease, marked the beginnings of a new global health (Chorev 2012; Brown, Cueto, and Fee 2006).

This interconnectedness was also evident in the increasingly globalised pharmaceutical market, where there were demands to harmonise regulatory standards. For example, the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) was established in 1990 as a result of cooperation between regulatory agencies and the research-based pharmaceutical industry in the USA, EU, and Japan. Among other things, the ICH sought to ‘eliminate duplication of work and procedures caused by different regulatory requirements and cut back on waste of resources’ (WHO 1999, 15).

The emergence of drug counterfeiting as a worrying new concern to WHO member states also occurred at a time of significant transition in the pharmaceutical markets of LMICs. Examining Nigeria, Peterson (2014) writes about how, from 1979, the country encountered an ‘oil bust’, following a period of relative prosperity in the 1960s and 1970s. As a result of changes in US monetary policy and the pricing

strategies of the Organisation of Petroleum Exporting Countries (OPEC), oil prices fell, precipitating a foreign exchange crisis that drastically reduced the money available to import drugs. This led to drug shortages across the country and the collapse of the previously vibrant Nigerian pharmaceutical market. Subsequently, informal markets blossomed in ‘the interstices of urban space’: on roadsides, in car parks, under bridges, and on buses (Peterson 2014, 21–22). Such markets became crucial for drug supply, even for public facilities such as hospitals. Regulators, manufacturers, and pharmacists warned that the growth of informal markets had dire consequences for drug quality, facilitating the spread of counterfeit drugs. The introduction of structural adjustment programs by the World Bank and International Monetary Fund in the 1980s, which demanded currency devaluation and cuts in public expenditure, added to the perilous situation. By the start of the 1990s, it is estimated, up to 70% of drugs in Nigeria’s pharmaceutical market were fake (Peterson 2014, 6).

As one of the largest pharmaceutical markets in Africa, Nigeria was particularly sensitive to these changes. It is unsurprising, therefore, that its delegation to the WHA was especially vocal about fake drugs. As early as 1984, they warned that ‘fake, substandard and dangerous drugs are circulating widely in the markets of developing countries’ (WHO 1984, 129). Nigeria’s repeated warnings about these drugs informed the WHO’s decision to list ‘counterfeiting’ as one of the problems requiring attention at the 1985 Nairobi Conference.

Analysing Nigeria’s deputations to the WHA, as well as other accounts, it is apparent that both professional anxieties and public health concerns formed part of the

constellation of fears around counterfeit drugs. Nigeria's delegations to the WHA included government officials trained in pharmacy, such as Professor Dora Akunyili, who narrated the spread of counterfeit drugs through their professional lens. As informal markets grew in Nigeria and other LMICs, professional pharmacists lost control of the wholesale pharmaceutical market to traders who were not professionally qualified (Peterson 2014). Their accounts were thus imbued with concern about loss of professional prestige and power.

Professional conferences were another forum through which concerns about counterfeit drugs reached an international audience. At the 1987 Commonwealth Pharmaceutical Conference in Kenya, Sam Agboifo, the former president of the Pharmaceutical Society of Nigeria, described how fake drugs were appearing in the Nigerian market. He exhibited what he claimed to be a fake antibiotic, lincomycin, alongside the supposed authentic article, made by Upjohn. The suspect product had the same batch numbers, expiry dates, and labels as the authentic product, but were sized differently. The spectacle was reported in *The Pharmaceutical Journal* and covered by the WHO's periodical, *Drug Information* (Anon 1987; WHO 1987).

Agboifo used the demonstration to argue for the strengthening of legislation and enforcement, and public education about counterfeit drugs. This example illustrates how, from an early point, concerns about counterfeits were not expressed solely in technical terms, but as a problem of criminal justice (Jayasuriya 1992). In June 1988, Agboifo wrote to the WHO about '[t]he very high incidence of fake, adulterated, counterfeit and sub-standard drugs' in Nigeria, and asked for the WHO's support to develop testing facilities (Agboifo 1988). Correspondence in the WHO archives

suggests that the problem of counterfeit drugs had been raised at professional conferences even earlier (Wehrli 1988). Thus, over time, through such correspondence, reports, and unveilings, the problem of counterfeit drugs reached an international audience.

The 1985 Conference on the Rational Use of Drugs responded to such concerns by recommending that the WHO should establish an ‘international clearing-house’ to study the problem further (WHO 1986a). The conference also asserted that ‘governments should take the action necessary to prevent drug counterfeiting, which was characterized by several participants as a criminal act that all drug regulatory authorities must try to combat’ (WHO 1986b, 21). In defining counterfeiting as a ‘criminal act’, the conference responded to the interests of the research-based pharmaceutical industry, represented at the conference by the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA). As counterfeiting affected the industry’s reputation and profits, it is not surprising that industry was a vociferous proponent of reform. The conference’s agenda was drafted with industry in mind, and—to avoid the fierce political lobbying that had accompanied earlier discussions of pharmaceuticals in the WHO—the list of participants was kept secret (Mamdani 1992). Ultimately, the conference seems to have proceeded amicably and, of all the issues on its packed agenda, the issue of counterfeit drugs was arguably the least controversial (Walt and Harnmeijer 1992). Following the conference, the WHO passed its first resolution on counterfeit drugs. This requested the WHO’s director-general ‘to initiate programmes for the prevention and detection of the export, import and smuggling of falsely labelled, spurious, counterfeited or substandard pharmaceutical preparations’ (WHO 1988).

The dimensions of counterfeit

The new discourse on counterfeit drugs had several notable features. Firstly, counterfeit drugs were presented invariably as a *growing threat* to public health, one whose parameters were *impossible to define*. A typical quote is the following, by the Executive Vice-President of IFPMA, Richard Arnold: 'It is impossible to assess the real scale of the problem. In many countries in Africa and South-East Asia, the widespread existence of fake products is only too evident' (Arnold 1989, 167). Rather than undermining expert knowledge, this uncertainty was intrinsic to how counterfeit drugs were conceptualised. It evoked danger and the urgent need for action, despite limited understanding of the scale of the problem. Counterfeit drugs were thought to be prevalent across both developed and developing countries, although the weakness of drug regulation in the latter was thought to make them especially vulnerable.

Secondly, as decreed by the Nairobi conference, and constantly repeated thereafter, counterfeiting was *criminal*. Hence, suspect drugs began to carry an additional connotation. In addition to controlling for drug quality, governments had to tackle the deliberate, insidious, and criminal enterprise that produced counterfeit drugs. Significantly, counterfeit drugs were defined not just by their appearance, packaging, or composition, but by something intangible, described by the IFPMA's Vice President for Scientific Affairs, Margaret Cone, as an 'intention to deceive' (Cone 1997). The criminals behind counterfeits remained elusive, although proponents of control speculated that 'unscrupulous' or 'unpatriotic' businessmen were behind the trade, motivated primarily by profit (Wehrli 1988). By the 1990s, WHO documents

began to implicate transnational organised crime, thought to be branching out from narcotics to an area where profits were high and the risks of being caught lower (WHO 1997; United Nations Office on Drugs and Crime 2009). Indeed, the WHO's interest in counterfeit drugs emerged alongside a broader global interest in illicit drugs and the so-called War on Drugs.

Thirdly, the counterfeit discourse signalled a threat to global health exterior to the legitimate pharmaceutical industry. Counterfeiting was seen to occur outside official distribution channels or to otherwise infiltrate it. This criminal business was pervasive, and it varied in sophistication, ranging from rudimentary cottage laboratories in the backrooms of shops to complex transnational networks with the tools, money, and know-how to reproduce the most expensive brand-name medicines. The amorphous and clandestine nature of the perpetrators added a further ambiguity to counterfeit drugs.

Fourthly, the discourse on counterfeits, through words such as 'trafficking' and 'smuggling', associated drug counterfeiting with other illicit trades. The rise of counterfeiting of all types was often conceived as a problem of modernity: a consequence of globalisation, increased international trade, and the growth of unregulated markets. The weapons developed to combat counterfeit drugs, therefore, were drawn from a similar arsenal.

Fifthly, the focus on counterfeit drugs marked a shift in the moral gaze. It largely displaced the focus on substandard drugs, allegedly being dumped in developing countries by companies based in the global North, to counterfeit drugs that were

seen to come from elsewhere. While this 'elsewhere' was vague, considering the complex outsourcing and licensing arrangements of the transnational pharmaceutical industry, developing countries with growing generic industries, such as India or China, were increasingly blamed. From the perspective of the research-based pharmaceutical industry, these were countries which failed 'to recognize the patents owned by the multinational drug companies' (Land 1992, 192).

This redirection of the moral spotlight influenced a final feature of the counterfeit discourse: a shift in the control regime around suspect pharmaceuticals. As Hornberger (2018) explains, the discourse on counterfeits heralded a transition from a regime of 'drug safety' to one of 'drug security'. While the WHO, pharmaceutical manufacturers, and other actors continued to draw upon public health to justify the control of counterfeit drugs, the problem was increasingly seen as one of criminal justice and supply chain security. Accordingly, police and customs authorities assumed a greater role in the international control of suspect drugs than previously. Demands also came for strengthened legislation and increased powers for existing actors, such as NDRAs (Jayasuriya 1992). In short, the terminology of counterfeit invited a new, more muscular approach to suspect drugs.

Amid these sweeping changes, it was only in 1992 that the WHO took concerted action against counterfeits, organising a workshop in Geneva in conjunction with the IFPMA. Attended by figures from industry, NDRAs, law enforcement, and various medical and pharmacy societies, this workshop was the first to formally define a counterfeit medicine, as: 'one which is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and

generic products and counterfeit products may include products with the correct ingredients, wrong ingredients, without active ingredients, with insufficient quantity of active ingredient or with fake packaging' (WHO 1992, 1).

As we have seen, an intrinsic feature of the way counterfeit drugs were conceptualised was an uncertainty about their prevalence. This presents something of a paradox, since if the true scale of the problem could not be known, how could it be understood as a problem at all? In practice, it was the reproduction of the claim that counterfeits posed a threat to public health—across a multitude of forums—that defined them as a problem. As already discussed, the WHA and pharmacy conferences were crucial vehicles for the elevation of concerns around counterfeit drugs. Another venue was the biennial International Conference of Drug Regulatory Authorities (ICDRA). As early as 1991, the issue of counterfeiting was raised by industry representatives; at the seventh ICDRA in the Netherlands in 1994, counterfeit drugs were the subject of a plenary session, including speakers from Glaxo, the UK Counterfeit Intelligence Bureau, and the Customs Cooperation Council.

Scientific journals and professional bulletins also played an important role in cementing the dangers of counterfeit drugs among their readerships. As part of its Revised Drugs Strategy, the WHO was requested to increase communications to member states. Subsequently, periodicals such as *Drug Information* became key outlets for the dissemination of concerns around counterfeits, reporting suspect drugs in circulation.

What is remarkable about this early discourse on counterfeits is the extent to which it was underpinned by hearsay. What little evidence there was on counterfeit drugs was largely assembled through the collation of anecdotal reports, including the WHO's own database on counterfeit drugs, established in 1982. Based on published accounts in health literature as well as reports submitted by NDRAs and companies, by 1997 this database included 751 cases of counterfeit drugs. However, these reports could not be validated. As one WHO official emphasised, 'this could only be done by painstaking research into each individual case' (WHO 1997, 8). In a very real sense, therefore, the threat of counterfeit drugs was constructed through the proliferation of reports, rather than the substantiation of actual cases.

WHO officials and correspondents recognised the paucity of international data on counterfeit drugs could act as a barrier to international action. For example, Murtada Sesay of UNICEF's Sierra Leone office wrote in 1993: 'One thing that still borders [sic] me is the lack of factual information on the magnitude of the counterfeit drug problem. I have no doubt in my mind, based on my previous work in this area, that the problem is grave, or potentially so' (Sesay 1993). WHO surveys in conjunction with a French NGO revealed 'the striking finding ... that no reliable independent or government data concerning the magnitude of the problem could be obtained' (WHO 1994, 18). John Dunne, the director of the WHO's Drug Management and Policies Division, wrote: 'It seems possible, simply as a consequence of lack of information and the failure of some surveys to yield positive information, that attention will be drawn away from a problem that in reality requires urgent and concerted attention' (Dunne 1994).

Admittedly, it was difficult for the WHO to estimate the prevalence of counterfeit drugs when the definition remained elastic and countries around the world had differing legal interpretations. Proponents of action against counterfeits maintained that variations in nomenclature and law among countries undermined a coherent international response. However, these problems of definition and quantification belied a more fundamental problem. As a phenomenon that could not be defined simply through laboratory assay or pharmacopeial standards, but rather through an array of vague characteristics, fake drugs were ‘unknowable’ (Hodges and Garnett 2020). International consensus failed to appear, not only around the definition of counterfeit drugs but also concerning their composition, prevalence, sources, distribution routes, and effects. Paradoxically, this ‘unknowability’ imbued counterfeit drugs with *further* menace, suggesting that the true scale of the problem remained hidden—deliberately so. Evidently, drug counterfeiters conspired to keep their activities secret.

A new paradigm of pharmaceutical quality control

By the 1990s, globalisation, the growth of the Internet, and increasingly harmonised international trade exposed the porous borders and deficient systems of regulation that were thought to encourage trade in counterfeit drugs. Conceiving of the problem in this way led to new forms of international cooperation aimed at reinforcing borders, strengthening enforcement, and bringing perpetrators to justice. It also created new ways of thinking about and dealing with fake drugs in the realms of criminal justice and border control.

The transition to what Hornberger (2018) refers to as 'drug security' is easy to exaggerate, for international public health—especially around contagious disease—always had a security element, and national drug regulation, to a certain extent, was a response to the threat of criminality. However, from the 1990s, actors unrelated to public health were brought into the control of fake drugs. The Permanent Forum on International Pharmaceutical Crime, a group of national pharmaceutical enforcement agencies largely based in the global North, was established in 1998. The pharmaceutical industry created the Pharmaceutical Security Institute (PSI), composed of the security departments of 34 corporations, to provide advice and training to member organisations (Nayyar et al. 2019). By the mid-2000s, Interpol was working increasingly with the WHO to combat the problem. A key moment was the 2006 WHO International Conference on Combating Counterfeit Medicines, in Rome, whose declaration mandated the creation of the International Medical Products Anti-Counterfeiting Task Force (IMPACT), with Interpol as a key enforcement partner (WHO 2006).

While international action against counterfeits increasingly took place in the spheres of criminal justice and trade, these new actors continued to use public health to legitimise their activities. Thus, drug security can be seen to have reconfigured, rather than displaced, previous concerns with drug safety. The difference is largely one of degree, as actors involved in the fight against counterfeit drugs increasingly assumed the aggressive guise and weaponry of the police or military. This is evident in the sweeping series of 'operations' IMPACT/Interpol conducted, such as Operation Mamba in Africa and Operation Storm in Southeast Asia (Interpol 2010, 2019).

Efforts to criminalise and disrupt pharmaceutical counterfeiting gathered pace in the late 2000s. In 2009, the former French president Jacques Chirac introduced the Cotonou Declaration in Benin, committing ‘doctors, pharmacists, heads of industry, jurists, State officials, citizens ... to the fight against the criminal economy of counterfeit medication’ (Fondation Chirac 2009). In 2011, a resolution on fraudulent medicine was adopted by the United Nations Commission on Crime Prevention and Criminal Justice, emphasising ‘the involvement of organized criminal groups in all aspects of trafficking in fraudulent medicines’ (United Nations Office on Drugs and Crime 2011). That same year, the Council of Europe signed the MEDICRIME Convention. Defining a counterfeit medicine as any medical product with a ‘false representation as regards identity and/or source’, to date it is the only international instrument to specifically criminalise the manufacture and supply of counterfeit medical products (Council of Europe 2011).

Under IMPACT, the WHO coordinated its activities with police and customs organisations to a much greater extent than before. This created new tensions. While WHO officials had emphasised that ‘criminal investigation is not part of the remit of WHO’ (WHO 1997, 10), WHO’s sponsorship of IMPACT invited criticism from the governments of countries such as India that it was more concerned with protecting the commercial interests of pharmaceutical companies than public health.

In summary, in the 1980s and 1990s, pharmaceutical companies, pharmacists, NDRAs, and other actors increasingly began to voice concerns about the spread of counterfeit drugs. The emergence of these drugs was linked in part to structural

changes in pharmaceutical markets (such as the increasing harmonisation of global trade and the impact of structural adjustment programmes), but also to professional and commercial anxieties, with pharmacists fearing loss of power and pharmaceutical companies fearing loss of profits. The danger posed by counterfeit drugs was signalled through the reproduction of these anxieties across a multitude of spaces. The inability of experts to fully comprehend the problem, rather than casting doubt on the extent of its existence, suggested that it was insidious. The association of counterfeiting with criminality led to a greater involvement of police and customs authorities.

Substandard/Spurious/Falsely-Labelled/Falsified/Counterfeit (SSFFC): The entanglement of intellectual property and global health, c.1994–2017

In the 2000s, numerous LMICs began to criticise the terminology used to define fake drugs at the international level. Many of the new tensions on display at the WHA, revolving around the term ‘counterfeit’ in the WHO’s lexicon, emerged due to a relatively new phenomenon: the internationalisation of intellectual property rights (IP). The subsequent entanglement of public health and IP concerns in the control of fake drugs generated a new field of political conflict. By erecting barriers to the international trade in generics, some governments claimed, the term ‘counterfeit’ undermined access to quality, efficacious, and affordable drugs.

To understand these tensions, we must look again to structural changes in the international trade and manufacture of pharmaceuticals. As evident from this article, the internationalisation of trade had long been a driver of the WHO’s normative activities in the pharmaceutical field. Globalisation, however, with its outsourcing and

licensing arrangements, and the increasing complexity of supply chains, added a new dimension to these efforts, with IP considerations becoming increasingly relevant. IP concerns not only surfaced in respect to public health emergencies such as AIDS and the need for poorer countries to obtain expensive, patented drugs. LMICs were increasingly implicated as important manufacturing bases in their own right. For example, India had assumed 'a central place in global pharmaceutical politics' by becoming a key source of low-cost essential medicines (Sunder Rajan 2017, 31).

Concerns about IP, it should be said, were certainly present before this time. For example, they were implicit in the correspondence of pharmaceutical companies with the WHO, in which the dangers of counterfeit medicines were highlighted. However, to assure cooperation with the WHO, and in the absence of an international mechanism for IP protection, pharmaceutical companies' concern with protecting patents, trademarks, and profits was often translated into different registers, such as public health and criminality.

The WHO was certainly aware of the industry's agenda. For instance, the 1992 joint workshop on counterfeit drugs was premised on the understanding that IP issues were not to be discussed; by excluding these issues, WHO could claim no conflict of interest, despite the workshop being financed by the IFPMA (ten Ham 1991). However, WHO officials failed to appreciate that the term 'counterfeit' was already laden with IP connotations. By not challenging it, WHO legitimised its use at the international level. This had serious consequences. As argued by the campaign group Third World Network, the 1992 definition of counterfeit dropped alternative

terms, such as 'falsely labelled', which had been used previously to describe fake drugs. This led to a narrowing of international debate, allowing IP issues to permeate international discussions (Gopakumar and Shashikant 2010).

Rising criticism about the use of 'counterfeit' was prompted by the signing of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in 1994, which established a mechanism to enforce IP internationally. TRIPS brought to the surface the IP considerations that had hitherto lurked beneath the public health rhetoric, introducing significant confusion to the WHO's mandate.

For critics, the WHO's sponsorship of IMPACT was a gross conflict of interest (Gopakumar and Shashikant 2010). At the 124th meeting of WHO's Executive Board in 2009, delegates from LMICs condemned IMPACT for its inappropriate relationship with pharmaceutical companies and law enforcement, its insufficient representation of developing countries, and its opaque governance and financing (WHO 2009). Terminology was central to this debate, with the argument that since 'counterfeit' was usually defined in an IP context, it could be applied inappropriately to generic drugs and used to restrict their trade. In this way, the language of counterfeit acted as a focal point for various grievances against the research-based pharmaceutical industry and access to affordable drugs in low-income countries.

The fear that international IP law could be used to curtail generics was not imaginary, since the pharmaceutical industry had attempted previously to enforce strict control over the pricing and licensing of drugs, for example for anti-retroviral drugs against HIV/AIDS in the 1990s. This conflict underpinned the 2001 Doha

Declaration, which reinforced provisions within TRIPS permitting countries to set aside the rights of patent holders in the event of a public health emergency (World Trade Organization 2001). As mentioned previously, from 2008 EU customs authorities seized shipments of Indian generics bound for countries such as Brazil and Colombia. While this trade dispute was eventually resolved, the negotiation of new international trade agreements, such as the 2011 Anti-Counterfeiting Trade Agreement, amplified fears that international IP laws could further restrict access to generics.

These debates reached a peak at the sixty-third WHA in 2010, where the cumbersome expression 'substandard/spurious/falsely-labelled/falsified/counterfeit' (SSFFC) was adopted. This term was adopted to placate competing national interests while allowing international action on fake drugs to continue. It was a belated admission by the WHO of the political conflict inherent in the technical determination of fake drugs. Ultimately, IMPACT unravelled. In response to mounting criticisms, the WHO was forced to dissociate itself from IMPACT, and the taskforce vacated the WHO headquarters.

Within the WHA, debate split along regional lines. African states such as Nigeria endorsed the existing definition of counterfeit, reflecting the centrality of this term in their legislation and cosmologies around fake drugs. Their relative lack of pharmaceutical manufacturers and reliance on imports also meant that the term retained acceptability (WHO 2010, 149). Southeast Asian states such as India and Thailand emphasised access to 'safe, efficacious, quality and affordable' medicines, demanding the excision of 'counterfeit': this reflected their support of their important

generic sectors. South American nations such as Ecuador, meanwhile, emphasised the risks of ‘falsified’ medicines in more neutral terms and called for enhanced global action against them.

In 2012, the WHO established a new Member State Mechanism (MSM) to coordinate international action on SSFFC drugs, bringing all 194 WHO member states under one umbrella. One of its first tasks was to identify what contributed to the emergence and spread of SSFFC medicines; this contrasted with IMPACT, whose programs leaned towards enforcement (WHO 2014). Critics of IMPACT have judged the MSM positively, claiming it has fostered international cooperation in a transparent manner and explicitly excluded IP considerations (private correspondence with K.M. Gopakumar, November 2019). However, budgetary difficulties have undermined its effectiveness, and difficulties in appointing a chairperson of the MSM’s steering group meant its activities were slow to develop. In tandem, a new Global Surveillance and Monitoring System (GSMS) was created to improve reporting on SSFFC drugs. Within its first three years of operation, more than 1,100 SSFFC drugs were reported by various NDRAs (WHO 2016, 2017).

WHO discourse around fake drugs continues to develop. In 2017, the WHA resolved to drop the contentious term ‘counterfeit’ from the WHO’s official lexicon altogether, adopting the streamlined terms ‘substandard and falsified’ (SF) in place of SSFFC. This decision indicated that a critical mass of member states now accepted that the inclusion of ‘counterfeit’ in WHO’s official lexicon had invited significant confusion. Nevertheless, the term continues to be in widespread circulation. Not only does it remain in use among many NDRAs (especially in Africa), but it continues to underpin

police and customs operations against fake drugs, as well as the work of various NGOs.

Conclusion

This history of the WHO's engagement with fake drugs contrasts sharply with the popular and scientific literature. Rather than taking the 'fakeness' of fake drugs for granted, I have taken it as a question to be asked. Stepping back from the chorus of claims around fake drugs (they present an immediate and pressing danger to global health, they drive antimicrobial resistance, India and China are the major sources of fake drugs worldwide, etc.), in this article I have addressed the wider issues at stake in their contestation and determination within the world's leading health organisation.

Given that fake drugs are highly 'fluid' objects, resisting simple categorisation or determination (Cloatre 2016), it is unsurprising that fake drugs have had a complex terminological journey within WHO. Nor is it surprising that the terms used to describe fake drugs have been fraught and contested, reflecting the role of various interests in their labelling and definition. These include pharmaceutical companies, keen to preserve patents and profits; the governments of LMICs, wishing to support their own generic industries and to safeguard access to medicines; professional pharmacists, eager to retain control over retail and distribution; and police, NDRAs, and customs authorities, seeking to justify their activities and strengthen their powers.

What this genealogy highlights is that the problem of fake drugs at the level of international (or global) health was shaped through evolving configurations of

political debates within the WHO and its decision-making body, the WHA. For example, in the febrile political climate of the Cold War in the 1950s, the WHO refrained from directly regulating the quality of drugs, although its constitution permitted it to do so. Instead, the WHO concentrated on developing a technical language of quality, which it advanced through measures such as the *International Pharmacopoeia*. In the 1960s, when newly independent nations joined the UN, the technical language of quality, alongside anxieties about drug safety, undergirded concerns about quality control and the dumping of substandard medicines into the markets of developing countries. By the 1980s, this moralistic concern was displaced, as attention increasingly focused on counterfeit drugs, which were framed as a problem of criminality and supply chain security. By the 2000s, the entanglement of intellectual property and global health, in the wake of TRIPS, ushered in another configuration of debates. Here, the focus on counterfeit drugs was seen to undermine the legitimate trade in generics, as countries such as India assumed a prominent role in the supply of low-cost essential drugs to developing countries.

The WHO's evolving nomenclature around fake drugs, therefore, reflects a kind of moving battleground as configurations of debates within the WHA shifted. Behind these lay various structural conditions: the growing market for pharmaceuticals, especially in LMICs; the increasing complexity of global pharmaceutical trade; the increasing surveillance of the global supply chain; and the formation of global health itself, as other actors (such as private donors and partnerships) became increasingly dominant in setting global health priorities. Debates about fake drugs were also shaped by economic trends and the dynamics of the international pharmaceutical

market. For example, the spread of fears about counterfeits in many LMICs occurred in the context of structural adjustment, currency depreciation, and the rapid rise of pharmaceutical prices. This resulted in drugs shortages and the concomitant growth of informal markets, which not only provided opportunities for drugs to be sold outside regulatory oversight, but also for new sorts of claims about fake drugs to arise.

In a similar way, the WHO's evolving discourses around fake drugs may also be conceptualised as a kind of market. Various claims and counterclaims have carved out space for a complex and ambiguous phenomenon, now widely considered to be a pressing threat to global health.

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