

**RESEARCH**

# Drug Problem or Medicrime? Distribution and Use of Falsified Tramadol Medication in Egypt and West Africa

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Tramadol is a synthetic opioid that is widely used as an analgesic for alleviating pain of moderate to medium intensity. With potency estimated to be about one-tenth that of morphine, tramadol is considered as relatively safe with regard to poisonings or dependency. Yet there are increasing reports of widespread non-medical consumption of tramadol in North and West Africa. The Egyptian government has requested the UN Commission of Narcotic Drugs to put tramadol under international control. This will have profound implications for the treatment of acute and chronic pain across developing countries where tramadol is often the only available analgesic, because controlled substances are impossible to obtain for health care practitioners. The tramadol sold outside of medical establishments is often adulterated and substandard, part of the massive trade in falsified medicines that is possibly far more devastating than the hedonic use of psychoactive substances. Yet the international machinery in place to control medical products is feeble and the penalties for medicrime are modest next to drug trafficking offences. The article suggests that international controls need to re-assess their priorities to focus on human and patient well-being. A further shift is needed away from repressive measures against consumers, to tighter regulation in the production and distribution of medications and pharmaceutical substances. This must involve a wide range of stakeholders, including health care practitioners, the pharmaceutical industry, pharmacists, patients associations, and the public at large.

**Keywords:** Tramadol; synthetic opioids; West Africa; Egypt; medicrime; regulation; pharmaceutical industry; Falsified Medicines

In March 2017, representatives for the Egyptian government submitted a conference room paper to the Commission on Narcotic Drugs (CND) in Vienna recommending ‘international cooperation in addressing the non-medical use and abuse, the illicit manufacture and the illicit domestic and international distribution of tramadol’ (CND 2017). In Egypt, according to the paper, the non medical use of tramadol has led to a rise in hospital admissions and mortalities. Though the medication has been under national control since 2012,<sup>1</sup> restricting access to medical users with the authorisation from a qualified health care professional, the Egyptian Anti Narcotic General Administration (ANGA) continues to seize considerable quantities of unlicensed imports. The government is therefore proposing to the United Nations that tramadol be placed on the list of controlled substances. This would mean that it can only be traded in the context of the international import/export authorisation system that is managed by the International Narcotics Control Board.

The Commission on Narcotic Drugs (CND) is the United Nations commission charged with supervising the application of the international drug control treaties. It is assisted by the International Narcotic Control Board (INCB), an ‘independent and quasi-judicial monitoring body’<sup>2</sup> that publishes annual reports on trends

<sup>1</sup> ‘Tramadol was later placed in the schedule II, and then currently, tramadol is already placed as schedule I according to the ministerial decree no. 125/2012 of the Egyptian drug law’ (sic) (CND 2017).

<sup>2</sup> INCB website, <https://www.incb.org/>, retrieved 02/04/2018.

in the production and use of controlled substances. In 2017 the INCB reported that: 'Trafficking in and abuse of substances not under international control remains a serious concern in a number of African countries. The available data suggest that the non-medical use of tramadol, a synthetic opioid analgesic, is growing, as evidenced by seizures in Central, North and West Africa' and that 'there was growing evidence of tramadol trafficking and abuse in the countries of the Near and Middle East' (INCB 2017: 95).

In support of its case, the Egyptian submission cites INCB reports from 2012–2015 on the increase in seizures of Tramadol 'diverted from international trade' (INCB 2012) and/or 'from domestic distribution channels, at the retail level, and through sales without the requisite medical prescription' (INCB 2013). It is noted that tramadol is 'controlled under national legislation on psychotropic substances and/or narcotic drugs in Bahrain, Jordan, Qatar and Saudi Arabia' (INCB 2015).

In 2014 the CND passed resolution 56/14 encouraging member states to take comprehensive measures to prevent and reduce non-medical use (CND 2014b). Both the Egyptian government and the CND are framing the issue of tramadol as a problem of 'drug abuse' that should be regulated in accordance with the Single Convention on Narcotic drugs, the treaty that serves as the foundation of the current international drug control system. The problem is summarised in the preamble of the treaty: 'narcotic drugs while indispensable for pain management can lead to addiction' (United Nations 1961). In response, the system has established a control bureaucracy to ensure that governments that are signatories to these treaties employ restrictive measures in their national jurisdictions, including the criminalisation and the enforcement of the unauthorised production, distribution, and use of listed substances.

While the Egyptian government and some of the international agencies argue that scheduling of tramadol is right because of the incidence of 'abuse', the international experience suggests that controls rarely address the public health problems that accompany non-medical use, but have a range of unintended consequences that may be far more harmful to public good. The question examined in this paper is whether the approach that has been proposed is the optimal response for dealing with the distribution of illicit tramadol. Moreover, is the bundle of interconnected problems surrounding the non-medical consumption of tramadol across Africa, really best responded to by framing it as a drug control issue?

## Methods

Field research was conducted in Botswana and Namibia, where the non-medical use of tramadol or other prescription medicines is largely unknown, and five countries in West Africa: Benin, Cote d'Ivoire, Ghana, Niger, and Nigeria. A mixed-methods approach was used, combining formal discussions with office holders in government agencies, senior management of private sector corporations, and professional associations with structured interviews and guided group discussions with health care professionals. The literature review included a discourse analysis of the Ghanaian media and international press reports to complement the reports and documents from official organisations. Structured interviews with non-medical tramadol consumers were held in recreational settings in urban and rural locations in Ghana (65) and Benin (7).

The work fell into two distinct phases, first, in November–December 2016, as part of a programming mission for the regional Anti-Trafficking programme funded out of the 11th European Development Fund. In the second phase from June–September 2018, further visits were made possible by support from the pharmaceutical company Grünenthal, one of the largest manufacturers of tramadol medication globally. Samples of illicitly sold tramadol branded medication were collected from Benin, Ghana and Niger for a qualitative assay at the Grünenthal laboratory in Aachen, Germany.

## Theoretical Orientation

While the intention of the research was to gather a comprehensive data set with which to inform policy makers in West Africa and international fora, the theoretical framing of this article was informed by three different traditions. First of all, theories of policy making and the arrival at decisions through spiralling iterative processes as proposed by Turnbull.

Secondly, it draws on the critique of centralised global institutions as inherently rational and benevolent actors (Mazower 2009), and merges insights from studies of origins and construction of the international drug control system (Bruun et al. 1975; McAllister 2000; Nadelmann 1990), with theoretical insights on social systems (Luhmann 2007). The role of the international agencies is predicated on a notion of benevolence and a normative concern with the well being of 'mankind'. While this does remain a theoretical aspiration, organisational concerns and mandates impose far narrower definitions where the interests of professional sectors can displace the public good. The role of international agencies in the drug control field has rarely been studied in the African context.

Thirdly, it draws on insights from the analysis of African states whose lack of capacity or operational weakness has obliged elites to forge alliances with external actors, 'extraversion' (Bayart 1989; Callaghy 1987). One of the presuppositions of the paper is that the institutional fragility of African states creates vacuums that international organisations can move into. In the process they are presenting and shaping the problems to which policy makers are invited to respond in accordance with their mandate and organisational interests.

### Understanding the popularity of tramadol in Egypt and West Africa

Non-medical tramadol use has been widely reported from Egypt, where it 'offers an affordable buzz', and where its reputed properties of raised alertness and sexual stamina are highly prized.<sup>3</sup> The attraction of prescription medicines lies partly in relatively low cost and ready availability (Table 1), but also in the comparative lack of stigma compared to other substances. Particularly in countries whose legislative systems are based on Islamic notions of justice with an injunction against psychoactive substances and where public codes of morality tend to condemn 'intoxication' as 'haram' or unacceptable, an opportunity opens up for moderately powerful substances that come with a medical alibi (Ghiabi 2018). According to one commentator, the 'pseudo-medical veneer protects the user from feeling they are involved in an activity that is haram' (Economist 2015).<sup>4</sup> Similar patterns of non-medical use of prescription medication are reported from other Middle East and North African (MENA) countries (INCB 2016),<sup>5</sup> the most prominent being Captagon (Laniel 2014). It is also of relevance for West African countries with large Muslim populations and strong Islamic influence.

There is no known licit production of tramadol in Egypt or anywhere else in Africa, and the bulk of both licit and illicit imports reportedly originate from India and China (GOE 2017: 2).<sup>6</sup> Up to 2012 at least the biggest seizures were reported in the seaports of Alexandria, Damietta, and Port Said (CND 2017: 2), but there are also overland trading routes across the long land borders with Libya.

Yet Egypt is not the only country affected. According to the World Customs Organisation, tramadol is the third most commonly seized 'psychotropic substance' after MDMA and methamphetamine, 'with 2,050 individual seizures, representing 18.1% of all seizures' (WCO 2016). In 2014 the third-largest seizure globally was one of 7.3 tonnes reported by Niger (WCO 2015), a country well integrated into the trading and trafficking networks linking the northern Mediterranean with the Sahel, which, according to analysts, consists almost entirely of illicit trade (Shaw & Reitano 2014).

As a landlocked country, Niger depends on its neighbours along the West African littoral for access to global markets. Cotonou in Benin and Lomé in Togo serve as entrepôts for the Sahel region, and have registered significant increases in tramadol seizures. Sold at prices that range between a third to half a dollar for a 225 mg tablet it is well within reach of wide segments of the population.<sup>7</sup>

There are reports about the increase in non-medical tramadol use from right across the region. In Nigeria the Afrobeat rapper Olamide Adediji brought out a hit song 'Science Student' featuring tramadol, while the Ghana pharmaceutical society has cautioned against the proliferation of Tramadol used in high doses of 200–250 mg (Citifmonline 2017).<sup>9</sup> The West African Epidemiological Network has reported tramadol to be the most widely used substance after cannabis across the region. The reasons given are familiar – for increased sexual performance or to increase stamina when performing long and physically demanding tasks (Salm-Reifferscheidt 2018).

**Table 1.**

Reported informal market prices for tramadol tablets <sup>8</sup>			
Benin	Packet of 10 tablet × 50 mg	400 CFA	€ 0.60
Ghana	1 tablet × 225 mg	2–5 Cedi	€ 0.30–80
Nigeria	1 tablet × 225 mg	100 Naira	€ 0.25

<sup>3</sup> These same properties are ascribed to 'captagon', which contains the stimulant amphetamine (Laurent Laniel, personal communication).

<sup>4</sup> Forbidden by the Koran.

<sup>5</sup> 'There continue to be indications of large-scale prescription drug abuse in the region' (West Asia, para 694).

<sup>6</sup> The drug was first marketed by Grünenthal, who remain the largest producer for European markets but only exports negligible quantities to Africa.

<sup>7</sup> In the UK pharmacies pay £ 2.58 for a box of 100 tablets with 50 mg of tramadol (personal communication).

<sup>8</sup> Interviews with street traders and consumers between June–September 2018.

<sup>9</sup> <http://citifmonline.com/2017/09/22/pharmaceutical-society-cautions-against-abuse-of-tramadol/>.

## Considering the impact and effectiveness of international controls

In the often emotively charged discussion over the impact of non-medical tramadol use, calls are often heard for government to take immediate action. The language used is emotive and rhetorical, with common reference to biblical imagery like ‘the scourge of tramadol abuse’ (Ebo’o 2018) or evocations of a ‘menace’ to the young.<sup>10</sup> Governments have responded by imposing sets of controls that vary between countries but are designed to counter the risks of abuse and addiction through aggressive interventions in the market. They mobilise the criminal justice system, particularly the police, dedicated law enforcement agencies, courts, and prisons to curtail the sale and use of tramadol. As these measures are being consolidated and extended, it is important that their impact on medical care is taken into consideration and the phenomenon of non-medical tramadol use is studied more systematically.

### *The impact of international controls on tramadol-using patients*

This is particularly important in view of the impact that international scheduling will have on the availability of tramadol for medical needs. The difficulty in accessing medication for the treatment of pain in many lower- and middle-income countries is becoming an issue of growing concern (**Table 2**) (Lancet Commission 2017). It is not the cost of opiate analgesics, but legal and institutional barriers that have reduced the availability of pain management medication across Africa. These barriers, it has been argued have been constructed by the ‘UN international drugs control agencies ... because they have spent 50 years focusing on the war on drugs and are often dominated by representatives from ministries of justice and law enforcement who do not traditionally take a health perspective’ (Hallam et al. 2014; Anderson 2010).

It has been recognised that the ‘burdensome regulations’ are causing delays in the supply chain (INCB 2016).<sup>11</sup> The prioritization of repressive measures has resulted in a situation where ‘the obligation to prevent abuse of controlled substances has received far more attention than the obligation to ensure their adequate availability for medical and scientific purposes, and this has resulted in countries adopting laws and regulations that consistently and severely impede accessibility of controlled medicines’ (WHO 2011).

As the main objective of these controls is to prevent any leakage of medicines into the recreational market, countries that produce and export controlled pharmaceutical products are required to ensure that ‘the

**Table 2.**

	Morphine	Hydro-morphone	Fentanyl	Methadone	Oxycodone	Pethidine
<b>Benin</b>	0.0002		0.0011			0.2068
<b>Botswana</b>	0.6052					0.4169
<b>Burkina Faso</b>	0.0190		0.0002	0.0138		
<b>Cote d’Ivoire</b>	0.0059					
<b>Egypt</b>	0.1251	0.0146	0.0152		0.0076	0.0014
<b>Ghana</b>	0.1163		0.0001			3.5549
<b>Nigeria</b>	0.0141		0.0000			0.0066
<b>France</b>	27.6484	0.1709	1.1246	12.9566	22.3535	0.0348
<b>United Kingdom</b>	22.8571	0.1467	1.2740	31.0654	19.9277	2.4830
<b>Country with the highest consumption</b>	Austria 213.4573	Canada 52.2194	Germany 4.9350	New Zealand 58.0380	US 194.4109	Barbados 26.7676

Sources: International Narcotics Control Board; World Health Organization population data.  
By: Pain & Policy Studies Group, University of Wisconsin/WHO Collaborating Center, 2015.

<sup>10</sup> With sometimes astonishing inversions of priority – one UNODC press release about tramadol ‘abuse’ in Sahel countries mentions en passant chronic food shortages. Action is needed, apparently, to stop children from using tramadol to suppress their hunger pangs, but nothing needs to be done to relieve the hunger (UNODC 2017).

<sup>11</sup> [https://www.incb.org/incb/en/news/press-releases/2016/press\\_release030216.html](https://www.incb.org/incb/en/news/press-releases/2016/press_release030216.html).

amounts exported must be within the limits of the total estimates that that country has sent to the Board' (UN 1961: 31).<sup>12</sup> This means that importing states have to submit their annual estimates of their needs for any pain medications that are scheduled under the drug control treaties to the INCB for authorization.<sup>13</sup>

Calculations for such assessments are complex exercises that need to factor in the dynamics of population growth, changing disease profiles with new conditions including HIV/AIDS, and the needs of an ageing population. Previous studies found that Senegal was requesting the same morphine quota since the 1960s, while Gambia, Guinea, and Guinea-Bissau, reported no opioid medicine consumption between 2006–2009. Liberia was not reporting to the INCB and is therefore unlikely to be supplied by legitimate exporters. Burkina Faso, Cote d'Ivoire, Mali, and Niger were providing estimates that would only suffice for treating a mere 1% of their estimated terminal cancer and HIV/AIDS patients. Nigeria, with a patient population of 173,000, imports quantities of opioids that cover the needs of 274 patients (HRW 2011).

Responsibility for submitting requests to the INCB lies, in most countries, with the Ministry of Health. They in turn receive requests from the purchasing department of the central medical stores of their national health service providers or from accredited private sector importers. A straightforward process on paper, the reality is beset by administrative difficulties. In Botswana, for example, a private sector wholesaler will apply for a permit to the Medicines Regulation Authority (BMRA). The process is expected to take up to four weeks for an import permit with a validity of three months. Then an order is placed with the South African importer, who in turn has to apply to the South African Health Products Regulatory Authority (SAHPRA), for an export license, a process that may take between four to eight weeks. By the time the order is despatched the import license may have expired, which means a new permit will have to be applied for. On other occasions, the South African importer may be short of stock and only send half the requested amount or only part of an order for several medicines. Once again, the shortfall can only be made up upon procurement of a new import permit.

In Namibia, wholesalers reported that the process may well take three months, provided that there were no mistakes in the paperwork, either by the private sector company or the regulators. But it had happened that importers would forward products that were coming close to their sell-by date, which were returned, for fear of not being able to sell them in time. In each case the wholesaler would have to commence the process again.

Encumbered by these requirements, companies sought to increase their stock, to be able to respond to requests in a timely manner and to avoid duplicating the paperwork. But that tied up capital and increased the risk of having stock left on the shelves. It is due to these various complications that countries often import only a fraction of the quantity of medical drugs that they requested in the previous year.

The burden is also experienced at a local level by dispensing pharmacists. In Botswana the Drug Registration Unit requires pharmacists to keep records of patients' prescription, details of the prescribing doctors, and the number of tablets sold. According to the secretary of the Pharmaceutical Society of Botswana 'Some of them [pharmacists] decide this is too much extra work, they don't want to be accountable. Because if the DRU comes and you have 10 units missing you have a big problem.'

In Ghana too pharmacists are discouraged from handling controlled medicines by the administrative effort involved (prescription check against name of doctor and stamp, storing of prescription, entry into book or software) and the physical security precautions (locked cupboards, regular stock checks) required. According to Secretary of the Pharmaceutical Society of Ghana, pharmacists are custodians of medicines, not charities, and need to keep an eye on overheads to remain financially sustainable. Besides, profit margins on tramadol medications are low, and patients presenting with pain are most likely to agree to pay for less effective alternatives such as nonsteroidal anti-inflammatory drugs (NSAIDS).

Tramadol, which in Botswana, Ghana, Namibia, Niger, and Nigeria is subject only to national controls, remains available upon prescription to fill a critical gap in the management of both acute and chronic pain, particularly for populations living at a distance from hospitals. The additional layers of control that would follow international scheduling will in all likelihood result in effectively removing the medication from the shelves. For pain patients, the implications are serious. In Egypt the restrictions imposed by successive

<sup>12</sup> To assist countries in their responsibilities under Article 13 of the Psychotropic Convention, the INCB circulates, each year, an updated list of prohibitions and restrictions on the export and import of substances. This is contained in Part Four of the Annex to the Annual Statistical Form ('green list').

<sup>13</sup> INCB provides all Governments, in the first quarter of each year, with form B (Annual estimates of requirements of narcotic drugs, manufacture of synthetic drugs, opium production, and cultivation of the opium poppy for purposes other than opium production).



legislation with sharp and well-publicised punishment for unauthorised possession have been already been criticised for further raising the barriers for cancer pain treatment and exposing patients to unnecessary risk by having to resort to the black market (Alsirafy et al. 2015).

### ***Strict controls do not eliminate availability***

In spite of these controls, Egyptians can still find tramadol. One study of 75 patients found that 'The new restrictive regulations did not limit access to the trafficked counterfeit tramadol which may harm cancer patients rather than benefiting them' (Alsirafy et al. 2014).

The question arises whether the proposed use of the criminal justice system – law enforcement efforts to disrupt markets with arrests, fines, and incarcerations – are effective for tackling a public health problem. Sanctions may deter licit suppliers, for instance wholesalers of pharmaceutical products, pharmacists, or doctors, from diverting tramadol medications. But the vast bulk of tramadol entering the market in Egypt and West Africa is illicitly imported through poorly controlled ports and across highly permeable borders.

To stress the point, a comparison with other drugs is instructive. Cannabis has been controlled in Egypt since 1865 (UNODC 2008) and has, at Egyptian behest, been under international control since 1925 (Ghiabi 2018). Yet, according to a 2015 prevalence study on substance consumption patterns among a sample of 115,107 persons, 15.91% reported cannabis use (Hamdi 2016). Clearly, for a significant minority, access to cannabis is not difficult even though a ban, backed up by the threat of punishments, has been in place for many years.

Possibly even more illustrative of the failure of repressive measures is the data on opiate use from the Egyptian substitution therapy feasibility study cited in the 2016 INCB Annual Report (INCB 2016). Of the 100,000 problematic opiate users, half are reportedly dependent on tramadol and the other on heroin. The availability of heroin and cannabis, both substances that have been under international control for decades, puts into question the effectiveness of the proposed international scheduling of tramadol for reducing its non-medical use.

### ***Adulteration and drug combinations***

It was further noted that the drug effect reported by some of the Egyptian informants, was difficult to reconcile with the known pharmacological action of tramadol. As with other opioids, the expected effect is somnolence rather than alertness, prompting the speculation that the smuggled tablets combine tramadol with 'a central nervous system stimulant' (Alsirafy et al. 2014). The suggested combination with other substances was certainly borne out by an unpublished Egyptian study based on the analysis of 300 seized samples. About half of the samples contained paracetamol, diazepam, metronidazole, or carbamazepine – and discrepancies between the dosage indicated on the packet and the actual content. Some of samples contained 540 mg of tramadol, well above the maximum recommended medical dose of 400 mg per day.

The energising effect is also reported by non-medical tramadol users in West Africa, where tramadol-branded substances are popular with drivers, motorbike taxis, and manual workers. 'Here in Africa you need to work really well ... So you have to take tramadol to be able to work hard to keep your job' (Salm-Reifferscheidt 2018). Journalists reporting 'tramadol stories' have collected little data about drug combinations or what other substances informants may be using. Nor have there been any reported attempts to analyse the actual content of tramadol-branded substances that are on sale in West African markets. In the context of this project, it was possible to obtain eight samples from the Forensic Police in Niamey, Niger, for testing at the laboratories of Grünenthal in Aachen, Germany. The analyses showed that seven were adulterated with other substances and did not contain the dosage indicated on the packet.<sup>14</sup> In fact, none of the samples found in West Africa was in compliance with international or national regulations for medical products.

### **Trafficking in falsified medicines**

Only recently have international organisations turned their attention to the trade in counterfeit, falsified, and substandard medical products. The WHO has warned that possibly over half of the medicines sold in Africa are substandard, falsely-labelled, falsified or counterfeit (SSFFC), with devastating consequences.

Using annual malaria case estimates, the WHO has calculated 'that substandard and falsified antimalarials contributed an additional 72,000–267,000 deaths (CFR adjusted case: 31,000–116,000 deaths) annually in sub-Saharan Africa' (WHO, 2017). In Africa, the impact of medicrime is far more serious than that of drug trafficking, even though, as tramadol shows, these two crime categories overlap.

<sup>14</sup> Grünenthal is a German pharmaceutical company that first developed and remains the biggest producer of tramadol.

Yet the response of law enforcement, policy makers, and the donor community remains lukewarm. The law enforcement units that made the tramadol seizures in Cotonou and Lomé were set up, trained, and equipped under the auspices of the United Nations Office on Drugs and Crime, often with funding from the European Union as part of the Global Container Control Programme. Yet, the objective of the units that are based in seaports along the West African coast was: 'to minimize the exploitation of maritime containers for the illicit trafficking of drugs, and other transnational organized crime activities.'<sup>15</sup> Intercepting falsified medicines is at best a by-product of their activities.

One of the reasons for this can be found in legislation. In West Africa only Burkina Faso and Guinea have signed up to the medicrime convention.<sup>16</sup> Elsewhere trading in falsified medicines is treated as an intellectual property crime. Penalties are fines and at best six-month prison terms. According to one organisation campaigning against the trade, 'the legislative system makes no distinction between drug counterfeiting and other forms of counterfeiting; they see it only as a violation of industrial property and do not take into account the serious harm it can do to people's health.'<sup>17</sup> The repercussions of this light touch approach are manifest on the ground, because, according to one officer at the UNODC regional office in Dakar, the low penal tariffs discourage law enforcement agencies from taking the offence seriously.

The West African Health Authority and the Economic Community of West African States (ECOWAS) are making efforts to push the issue up the policy agenda and have set up a Medicines Anti-Counterfeit Committee (EMACCOM), but these regional initiatives are still at an early stage of development. Better progress is made at national level, with dedicated agencies in Ghana and Nigeria leading the way in setting standards for regulatory agencies. Nigeria's National Agency for Food and Drug Administration and Control (NAFDAC) is under the authority of the Ministry of Health with a mandate to 'regulate and control the manufacture, importation, exportation, distribution, advertisement, sale and use of food, drugs, cosmetics, chemicals, detergents, medical devices and packaged water.'<sup>18</sup> To achieve this, NAFDAC runs public awareness campaigns, certifies and inspects manufacturers and importers, checks imports at points of entry and conducts surveillance operations at markets and retail outlets. Critical for effective pharmarco vigilance is close cooperation with industry, retailers, and the public, all working on the understanding of having a shared interest.

Surprisingly, perhaps given the significance of the issue in terms of public health is the paucity of support from the international community combating the trade in falsified medicines. It is particularly noticeable when compared to the generous assistance lent to fighting illicit drug trafficking.

### The international enforcement mechanism for Drug Control vs. Medicrime

Though there is neither coca nor poppy cultivation in West Africa and no cannabis export, the region has been identified as a significant transit corridor. Information on the through-flow of drugs, principally cocaine, to markets in Europe has been compiled principally by UNODC (UNODC 2013), unlocking considerable EU funding.<sup>19</sup>

Strong legal provisions are in place against the production, distribution and consumption of 'narcotic' or psychoactive 'drugs', in clear contrast to the weak legal provisions governing medicrime. Governments and policy makers are much more likely to get international support if they pass a request through the drug control mechanisms than those for the regulation of medicine or in the interests of public health.

This is evidence of the amounts of support the European Commission, the largest development cooperation partner across West Africa, has been making towards 'drug control' and efforts to combating medicrime respectively (**Table 3**).

UNODC is in the strong position of being firstly, the centre of data gathering, analysis, and dissemination on drug flow information, and secondly, the management agency handling the implementation of donor funded projects. These are often intended to raise capacity of national or regional agencies, such as the Drug Control Unit within the Economic Community of West African States. Nigeria and Ghana have established the National Drug Law Enforcement Agency (NDLEA) and the Narcotic Control Board (NACOB), respectively, with a narrow focus on combating illicit drugs, modelled on the US Drug Enforcement Administration or

<sup>15</sup> UNODC, GCCP website accessed 01/04/2018 <https://www.unodc.org/ropan/en/BorderControl/container-control/ccp.html>.

<sup>16</sup> An international convention criminalising the production and distribution of counterfeit medical products adopted in 2010 by the Council of Europe and with 47 signatory states to date. <https://www.coe.int/en/web/medicrime/the-medicrime-convention>.

<sup>17</sup> IRCAM, <https://www.iracm.com/en/fake-drugs/problematic/> accessed 04/05/2018.

<sup>18</sup> NAFDAC <https://www.nafdac.gov.ng/> accessed 04/05/2018.

<sup>19</sup> Concerns have been raised over the "dual role" of UNODC as the main information provider and commentator on drug trafficking in West Africa, as well as the largest management agency of drug control programmes (Klein 2014).

**Table 3.**

EU-funded projects in West Africa 2013–2016				
Drug Control			Medicrime	
	Project name	Actions		
	Support to ECOWAS Regional Action Plan on illicit drug trafficking, related organised crime and drug abuse	Airport Communication Project (AIRCOP 1–3)	Seaport Cooperation Project (SEACOP 1–4)	Responding Effectively to Production and Trafficking (REPT)
	Assist the ECOWAS Commission and its Member States in the prevention of drug trafficking and drug abuse	Build drug-interdiction capacities at international airports	Build drug-interdiction capacities at international seaports	National strategies; inter-agency cooperation; capacities of pharmacist inspectors, law enforcement agencies, judicial authorities
<b>Countries covered</b>	ECOWAS	West Africa, Caribbean, Latin America	West Africa	Selected countries in West, Central, North Africa, Middle East
<b>Budget €</b>	16.5 million	7.6 million	9 million	4.9 million

the Egyptian ANGA. Other countries have specialised units such as the Office Central de Répression du Trafic Illicite des Stupéfiants in Niger.

These agencies are the direct partners of EU, but particularly US, law enforcement counterparts. They also get the opportunity to participate in donor-funded transnational operations that are organised and coordinated by international agencies including White Flow (Interpol), COCAIR (WCO/Interpol/UNODC), or Ailes Africaines (France).

Senior officers can also take part in the regular meetings of the international drug networks, for example the Heads of National Drug Law Enforcement Agencies, (HONLEA), for coordination, information exchange and planning.<sup>20</sup> The most significant meetings at a policy level are those organised under the auspices of the CND, either in Vienna or in New York, as for the United Nations General Assembly Special Session on Drugs (UNGASS) in 2016. These meetings are now routinely attended by the NDLEA.

There are no comparable mechanisms or platforms for tackling medicrime. In West Africa the basis for regional cooperation is the 2013 Niamey Declaration against counterfeit medicines in Africa, which, at best, amounts to an expression of intent, with no binding commitment and no funding allocation.

At the UN there is no special commission that concerns itself with the production, distribution, and use of falsified medicine, thus there is no pressure on states to adhere to international treaties and comply with the agreements. There are no agencies created specifically to monitor compliance and report breaches and malfeasance to the UN Economic and Social Council. The only international legal instrument, the Medicrime Convention that was sponsored by the Council of Europe in 2010, has only three African signatories and no compliance mechanism.

The best hope of international cooperation at present is via the WHO Rapid Alert System for information sharing on poor-quality medicines between medicines regulatory authorities. But the pharmarco vigilance systems in some West African countries are rudimentary, and with no mechanisms for cross-border cooperation they are ineffective against the intra-regional trade in falsified medicine.

### Conclusion: Reframing Tramadol

Keeping in mind the ultimate objective and original *raison d'être* of drug control, the prevention of non-medical use of habit-forming drugs (Single Convention on Narcotic Drugs 1961) it appears that law enforcement agencies are being nurtured as the principle champions for public health objectives. One consequence of this has been that policy makers, possibly at the behest of or in consultation with the dedicated drug law

<sup>20</sup> The 27th HONLEA, Africa meeting, in Hurghada, Egypt, 18 to 22 September 2017, discussed the trafficking of tramadol and law enforcement responses (INCB 2017).



enforcement agencies, avail themselves of control at the expense of other policy options. It also opens the door for attempts at using public health as a pretext for introducing political, social, or cultural controls or for advancing institutional interests. The authority of a global regime that follows the international scheduling of a drug like tramadol provides an alibi for the repressive actions of even unpopular regimes.

The international forum also provides an opportunity for justifying and normalising policies that have emerged from practice. It has been suggested that policies follow a spiralling, rather than a linear, trajectory, with policy actors at different stages continually reformulating problems in order to adapt and legitimise their actions (Turnbull 2013). The interplay between international and national agencies is interesting in this process, as INCB and national drug control and law enforcement agencies have been reinforcing one another in casting tramadol as a 'narcotic', impelled by the gravitational pull of the drug control system and political expedience of unleashing the repressive measures (raids, seizures, arrests) that have now become normalized in the drug control field.

Yet in the case of tramadol there are four distinct arguments for taking an alternative approach.

1. Patients – The international scheduling of tramadol will close down access to legitimate sources of last remaining stage 2 analgesic for millions of patients across Africa and other low and middle income countries.
2. Medicrime – The unlicensed trade in falsified tramadol branded medication is a medicrime, part of the global trade in falsely-labelled, falsified, or counterfeit medicines that is having a far more devastating effect than the controlled drugs, and needs a systemic response beyond the focus on repressive actions.
3. Social costs of repressive measures – Conventional drug control has been both ineffective and costly in terms of collateral damage. Large numbers of people, usually young men, are arrested, often brutalized, pushed through courts and prisons, with many ending up in lifelong criminal careers.
4. Supporting Medicine Standards Authorities – National and regional systems for ensuring the quality of medications are effective in improving public health and reducing the availability of all falsified medications, including tramadol. Extending the regulatory web with a clear focus on public health, mobilising professional groups and the public, will effectively combat organised crime by reducing the scope of criminal opportunity.

Instead of including tramadol in the international schedules, regional and national agencies should be assisted in ensuring the continued availability for medical practice. At the same time, the authorities should cooperate with key stakeholders and the international community to curtail the inflow of falsified medicines into the region. Better interception at points of entry and choke points is a good start, but ultimately, better cooperation is needed with partners at the point of origin.

Under the auspices of the Cocaine Route programme, the EU has already funded joint law enforcement investigations into cocaine trafficking between Latin America and West Africa. There is a strong argument for these mechanisms to be used in investigating the import of substandard and adulterated pharmaceutical products from India and other source countries. But it will require a reassessment of threats and opportunities, a rethink of policy objectives and the departure from a set policy path that has by now established its own momentum. One first step is, therefore, to shift the frame from 'drug' control, with all its baggage of vested interest and contested assumptions, and set it around the key problem at hand – the problematic use of tramadol (and other prescription medicines) stems from the illicit production and unauthorised importation and distribution of substandard and adulterated products. The suitable definition and the most promising approach is to treat it as a medicrime.

## Abbreviations

ANGA	Anti Narcotic General Administration
BMRA	Botswana Medicines Regulation Authority
CND	Commission on Narcotic Drugs
INCB	International Narcotic Control Board
MENA	Middle East North Africa
NSAIDS	Nonsteroidal anti-inflammatory drugs
SAHPRA	South African Health Products Regulatory Authority
SSFFC	Substandard, falsely-labelled, falsified or counterfeit
UNODC	United Nations on Drugs and Crime

## Competing Interests

Data was gathered over several field visits to West and Southern Africa over 2016–2018. The first were undertaken in the context of an European Development Fund supported programme “Fight against Organised Crime in West Africa: addressing all types of trafficking”. Subsequently funding was obtained from the pharmaceutical company Grünenthal. The author was free in the use of the data and the analysis is entirely his own.

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