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Andres Roman-Urrestarazu
Editors

Novel Psychoactive Substances

Policy, Economics and Drug Regulation

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This book is dedicated to all those who fear the change: see the opportunity and face the challenge

Foreword

Illicitly used synthetic drugs present a distinctive challenge to international drug control efforts. Unlike drugs such as heroin and cocaine, which are derived from plants and for which the sources may be geographically constrained, synthetic drugs can be manufactured anywhere. At the 53rd session of the United Nations Commission on Narcotic Drugs (CND) in 2010, the international community noted in CND resolution 53/11 entitled *Promoting the sharing of information on the potential abuse of and trafficking in synthetic cannabinoid receptor agonist* the increasing reports of the production of substances, most commonly herbal mixtures, containing synthetic cannabinoid receptor agonists (SCRAs) with psychoactive effects similar to those produced by cannabis. Within 2 years, CND resolution 55/1 (2012) entitled *Promoting international cooperation in responding to the challenges posed by new psychoactive substances* (NPS) expressed concerns about the risks that these substances may pose to public health and safety, while acknowledging the dynamic and fast-paced nature of the NPS market.

In what has often been described as an unprecedented phenomenon in international drug control, 94 member states and territories, in every region of the world, reported the emergence of over 348 NPS, by the end of 2013. Three years later, this number has more than doubled to 744 substances reported by over 105 countries and territories worldwide. A market which was initially characterized by SCRAs ('Spice') and synthetic cathinones ('bath salts') has evolved rapidly to encompass the entire range of effects and categories of traditional illicitly used drugs, for example classic hallucinogens, dissociatives, opioids, sedatives/hypnotics, stimulants and synthetic cannabinoid receptor agonists.

Of increasing concern are the risks and adverse effects to public health associated with NPS, including the harm to young people and other vulnerable populations. While NPS use may be lower than that of traditional illicit drugs such as cannabis and amphetamine-type stimulants, significant threats to public health, including emergency room admissions and fatalities, are increasingly being associated with NPS. Notable recent events include reports of an increased risk of HIV and HCV infections among stimulant NPS users and the rising number of

overdose events, including fatal intoxications, among users of fentanyl derivatives and other opioids.

Efforts by the international community over the past few years to address the NPS issue have been multifaceted, comprehensive and balanced. A total of eight resolutions of the CND from 2010 to 2017 have provided the basis for response in several fronts including raising of public awareness; public health intervention; national legislative responses; bilateral and multilateral sharing of data and information; law enforcement interventions, including control of chemical precursors used for manufacturing NPS; enhancing forensic capacity to facilitate identification and detection; early warning systems to enhance the preparedness of countries; and research to enable a better understanding of the problem as a first step to formulating effective scientific evidence-based polices.

The international drug control system was set up to protect human health and welfare by preventing drug abuse and dependence, and ensuring access to drugs for medical and scientific purposes. Over the past few years, the flexibilities enshrined in the provisions of the international conventions on the scope of control of substances have been successfully adapted to suit some of the peculiarities of the NPS phenomenon.

For example, *discretionary provisional control measures* prescribed under the 1971 Convention, which in situations of urgency allow for the establishment of temporary control measures to prevent widespread abuse before bringing a substance under international control, were applied for the first time in 2014, for mephedrone. Subsequent decisions by the CND from 2015 to 2017 have led to the scheduling of the most harmful NPS on the market, including some stimulants (synthetic cathinones and piperazines), SCRAs, opioids, sedatives/hypnotics, hallucinogens and dissociatives. In addition, some precursor chemicals used for the illicit manufacture of fentanyl derivatives were also placed under international control in 2017.

Notwithstanding these initial successes, difficulties in the detection and identification of NPS and the paucity of information on their adverse health effects continue to hamper efforts in establishing the necessary evidence base for robust scientific evaluations and subsequent international action as it will be highlighted in this book. The co-editors Dr. Corazza and Dr. Roman-Urrestarazu have decided to invite many of the world leading experts to contribute chapters to better inform on the current NPS regulatory regime and thus complement efforts at the international level in responding to NPS. Authors outline how several countries have adopted a wide variety of legal approaches and administrative measures—a reflection of the diversity and heterogeneity of the problem in different parts of the world.

In 2016, countries convened in New York for the United Nations General Assembly Special Session (UNGASS) on the world drug problem—an opportunity to review the progress made in the implementation of the 2009 *Political Declaration and Plan of Action on International Cooperation towards an Integrated and Balanced Strategy to Counter the World Drug Problem*. NPS, absent from the discussions leading to the 2009 Political Declaration and Plan of Action, featured

prominently as a significant threat in the current era. In the outcome document entitled *Our joint commitment to effectively addressing and countering the world drug problem*, member states resolved to '*strengthen national and international action to address the emerging challenge of new psychoactive substances, including their adverse health consequence'*. Key issues identified in the operational recommendations included the importance of enhancing information sharing and early warning networks, developing appropriate national legislative, prevention and treatment models and supporting scientific evidence-based review and scheduling of the most harmful, prevalent and persistent substances.

Providing an outlook towards the 2030 Agenda for Sustainable Development, the Outcome Document notes that 'efforts to achieve the sustainable development goals (SDGs) and to effectively address the world drug problem are complementary and mutually reinforcing'. To achieve SDG 3 on *good health and well-being*, early detection of NPS and their associated health risks is key to strengthening the prevention and treatment of substance abuse (Target 3.5). This would require monitoring systems capable of supporting health and emergency services, and early warning systems, particularly in developing countries (Target 3.d), to communicate the associated risks. Concerted efforts will continue to be required for the exchange of information and sharing of best practices, which can readily help countries make informed decisions and enhance their preparedness to address associated threats. Such efforts will strengthen the scientific evidence-based, balanced, comprehensive and integrated approach to drug policy that will ultimately reduce demand and restrict supply. A major future challenge would be how to maintain these efforts and find effective and prompt solutions in dealing with the dynamics and evolution of the NPS market.

It is vital in this regard to foster sharing of experiences and lessons learned at national and regional levels in instituting a variety of legislative, regulatory and administrative measures to address the NPS issue. It is also important to promote a better understanding, through research, of the trends, use and associated challenges of these substances in emerging sectors such as prisons, sports and among vulnerable populations. This would be a necessary first step in designing effective policy responses.

The current book supports these objectives. Whether you consult chapters of special interest or read the entire book, you can be assured that you will have been exposed to the most comprehensive summaries yet available on several national and regional policy responses to NPS and challenges associated with their use in settings such as prisons and sports.

Laboratory and Scientific Section
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Justice N. Tettey

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We owe a special gratitude to Dr. Justice Tettey for his support and inspiring foreword, which carries a strong message of international cooperation and multidisciplinary working to face the NPS challenge also in emerging sectors such as prisons, sports and among others vulnerable populations.

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Editorial Introduction: The Proliferation of NPS as a 'Game Changer' for Public Health Policy

Over the last decade, there has been a dramatic and unprecedented increase in the number of new drugs discovered and synthesized which has become a matter of global concern and a serious threat to public health. As known, hundreds of novel psychoactive substances (NPS) have become rapidly available in the drug market with barely any previous knowledge or experience about their side effects and toxicity and the health risks that they may pose to users. Misleadingly called 'legal highs', NPS are often advertised on the Internet as 'legal and safer' alternatives to illicit drugs, and they appear in increasingly sophisticated chemical structure with potential widespread and long-term effects on users' health. The EU Early Warning System currently monitors over 560 new substances, with over 70% of these identified in the last 5 years (EMCCDA 2016), and by July 2016, 102 countries and territories had reported over 644 NPS to the UNODC 'Global Synthetics Monitoring: Analysis, Reporting and Trends (SMART) Programme' far exceeding the 234 substances currently scheduled under the International Drug Control Conventions.

In this book we will discuss how the proliferation of NPS represents a 'game changer' for authorities, enforcement agencies, public health officials and clinicians. As a collective effort, we will provide a multidisciplinary analysis of how such a global phenomenon has challenged drug policy and raised new questions about policy governance and whether the existing domestic and international drug control systems are capable of responding in a timely and effective way. It will be discussed that policymakers, in an attempt to safeguard public health, have often responded in what might be considered an 'outdated' way to a completely new situation, with the most common response being prohibition. This approach has ranged from banning specific substances ('List Model') and chemical structure families of different classes of compounds ('Analogue System Model') to introducing a 'blanket' ban ('Generic Legislation Model') based on the broad notion of psychoactivity as in the United Kingdom, Poland and Ireland. Attention will also be paid to the cases of New Zealand, which piloted an unprecedented licencing system, Kazakhstan and the less explored diffusion of NPS in the Middle East.

The assumptions on which the scheduling framework rests and came to existence on the basis of different international drug control treaties will be a recurrent theme across the book, and relevance will be given to its guiding principle of 'public health harm', which needs to be demonstrated before a substance can be scheduled. The limitation of current risk assessments often based on poor or no scientific evidence will also be covered.

Another important topic of discussion will be the role played by the digital world in driving this rapid change and providing an accessible and efficient mechanism for global marketing and the sale of drugs. It will be argued that the Internet not only has facilitated access to information on chemical synthesis, which has enabled amateur chemists to stay ahead of the regulators by manipulating chemical structures to evade the law, but has also enabled the sharing of experiences between consumers, with sites hosting several discussion fora and providing mechanisms for buyer feedback and ratings. Attention will also be given to its most hidden aspects, such as the spread of NPS in the *deep* and *dark* web.

As a result of this analysis, it will become clear to the reader how the emergence of NPS is not an entirely *new* phenomenon per se as the recurrence of old substances into new markets has been seen before, such as in the case of kratom or *Salvia divinorum*. Indeed, although some substances have a very long history of human consumption (e.g. coca or opium), the arrival of new ones (e.g. LSD in the 1940s), or new forms of old favourites (e.g. heroine in the twentieth century and now morphing into carfentanyl), has always been part of the ongoing story of the human engagement with psychoactive substances. Arguably, this has been an accelerating trend throughout the twentieth century and especially in the post-war period. Evidence of this exists in the 1961 UN Single Convention on Narcotic Drugs' list of 85 prohibited substances, while in 2013 there are approaching 250 banned under the UN Conventions with the list of scheduled substances growing every year. Nevertheless, as outlined in all contributions of this book, the issue referred to as the 'NPS problem' is different in nature, to such an extent that we can accurately talk of entering a new phase in the evolution of global drug problems.

The aim of this book is to shed new light on the 'NPS problem' and to open up the possibilities for creating effective alternatives to current regulatory approaches and as the default position for drug policy and criminalization. Current approaches, based on a lack of evidence-based policy, do not seem to fit the nature of this complex phenomenon, while there appears to be little justification for purely criminal justice-oriented approaches, which prosecute people who do not consider themselves as 'drug users' in a traditional sense and include new categories of users such as athletes. The development of such new trends in drug supply and consumption requires novel frameworks of understanding together with a new preventative public health approach.

Each contribution in this book presents key and unique aspects of such a complex phenomenon as follows.

The contribution by Tettey and Levissianos captures the main features and trends of the NPS problem from a global perspective, and it explores how this has become a potential threat to public health and safety. It explores how NPS continue

to emerge on the market at a fast pace and shows how a rapidly developing NPS market has been able to adapt to all institutional responses and has become a serious threat to public health and safety. It refers to the pioneering work carried out by the UNODC *Global Synthetics Monitoring: Analysis, Reporting and Trends* (SMART) Programme in order to enhance the capacity to generate, manage, analyse, report and use information related to NPS to design effective policy and programme interventions. It discusses how from an almost exclusive European phenomenon, NPS have become a global challenge in over 80 countries, including facts that have come into light in Australia, East and Southeast Asia and elsewhere. The discussion is enriched by an overview of the prevalence studies that have been conducted in various countries around the world and argues how the absence of a common terminology on NPS has impeded the generation of comparable data across countries so far. The work concludes by highlighting the need for a wider and common understanding of the spread of these substances and more information on their composition and potentially harmful effects. The authors emphasize various institutional responses as countermeasures to this wave of threat and press for the need for better understanding of NPS through information sharing and the case for uniformity in universal terminology for NPS to facilitate the former effort.

The contribution by Stiegel categorizes current European Union legislation discussing the challenges of drug policy in the field according to the danger that NPS pose to public health and how European authorities have dealt with the challenge of an ever-expanding number of NPS available. It discusses current initiatives of tackling the problem and how the current framework has dealt with the issue in the European Union.

The contribution by Collins examines more closely the governance and politics surrounding the regulation of NPS and the role international organizations could play in this debate. Consequently, the author offers a preliminary list of features for good global drug policy governance based on the current assessment of the NPS discussion. It discusses how the challenges are often expressed in the form of differences in views on the policies themselves. It proceeds to describe how, although rarely the focus of attention, it is likely that the international governance of drug policy, how it is developed, overseen and assessed by international organizations, influences both the character of policymaking and the types of policies designed. It proposes how by critically reviewing the global governance of drug policy, it may be possible to identify changes that could improve the policymaking process and drug policy outcomes. To begin the process of exploring what may be needed to establish good governance of drug policy, the author discusses the current state of affairs providing incisive insight into the subject. This work develops a preliminary list of characteristics for good global governance of drug policy and compares this to the current state of affairs.

The contribution by Mazzoni, Barroso and Rabin explores the diffusion of NPS and other similarly marketed substance such as performance and image enhancing drugs (PIEDs), among elite athletes. Authors discuss the challenges posed by the phenomenon in the sport context and highlight the gaps presented by the list of

substances and methods prohibited in sports in and out of competition. Many of these are legitimate medicines, while others are counterfeited products sold through the Internet, including anabolic steroids and stimulants. It argues how in recent years, there has been a significant increase in the number of doping cases with illegal stimulants related to amphetamines and cathinones as well as new synthetic cannabinoids. Overall, the authors evaluate how the detection of new drugs represents a challenge for doping control, as methods have to be constantly adapted for their detection. It concludes by encouraging the development of intelligence-based approach, aiming at identifying and purchasing NPS as well as counterfeited products, to identify their chemical structures and assess their quality and purity with the objective to facilitate their identification and detection sometimes even before they appear on the market.

The contribution by Wilkins, Rychert, Byrska, Van Hout, Corazza and Roman-Urrestarazu looks at how New Zealand, Poland, Ireland and more recently the United Kingdom have enacted different laws with the intent to deal with the proliferation of NPS. This work presents an unprecedented comparative assessment of the laws in these countries and presents their goals in terms of harm reduction. It focuses on how such regimes addressed the harms of the NPS market, including in one case a framework for licencing NPS that prove to pose a low risk of harm to the public and in the other an overall prohibition based on the psychoactive effect of an NPS. While doing so, it provides new insights on the effects that regulated drug markets or upfront prohibition can have for governments, policymakers and producers, when applicable.

The contribution by Soderholm discusses how Middle Eastern States have found themselves at a critical juncture with regard to the emergence of NPS. Drawing on the history of regulatory systems for illicit drugs in the region, international scholarship on the impact of drugs on governance and development, and the formal and informal regulatory systems adopted by member states, this work charts possible future directions of NPS policy in the Middle East. It presents an historical evaluation of regulatory systems, and lessons are drawn from the emergence of the lucrative and violent trade for opiates in the 1970s, coinciding with rising Western demand and 'prohibition'. It questions the impact of emergency scheduling powers on reducing use, harm or trafficking in NPS and draws on the cases of khat and Captagon. While challenging the goals of drug control, it concludes by encouraging further attention to the idiosyncratic models for regulation based on the complex local dynamics of the NPS trade in the Middle East, as states risk catalysing a renewed 'war on drugs'.

The contribution by Prilutskaya and Chan describes the main features of the drug situation in the Kazakhstan addressing the NPS problem. Designer drugs emerged in the country 8 years ago in the context of traditional drugs' continued challenges. The new trends of illicit drug market have caused complex issues for policymakers and public healthcare providers in Kazakhstan and other countries in Central Asia. The current difficulties refer to the unlimited variability of NPS chemical formulas and complexity of lab detection in a low- and middle-income country setting. The law enforcement reform to deal with NPS was undertaken in 2015 introducing the

concept of drug analogues that was enacted as a main policy measure. State healthcare providers have also faced increasing numbers of patients suffering from NPS abuse/addiction. This has led to increasing pressure to set standards of clinical management improving at the same time monitoring systems for NPS. This analysis concludes by discussing the urgency to establish toxicological laboratories and create database enabling international information exchange, improving therefore evidence-based effective and ad hoc innovation measures.

The contribution by Shafi, Gallagher, Punukollu and Martinotti discusses how while there is a growing amount of evidence about risks and consequences of NPS use, very little has been done to link clinical evidence to policymaking as most evidence has been casuistic and there is no serious epidemiological evidence of the impact that NPS have had to public health. By presenting the case of a group of clinicians based at the Camden and Islington NHS Foundation Trust in London, it explains by giving concrete examples how most clinicians have faced serious challenges to diagnose, treat and manage patients with NPS problems and health authorities have not been able to provide adequate guidance as to the dangers of NPS. It argues how clinical toxicological reports are scarce and do not capture the clinical complexity that NPS pose, since no data is available in relation to the risks they pose to patients and public health. The main consequence of this has been that limited clinical evidence has been used in most global regulatory responses to NPS. It also discusses how a cycle of evidence should inform any serious public health decision and should also contain measurable clinical data together with information sharing practices at a national and international level. It concludes by encouraging effective clinical information data sharing initiatives.

The contribution by Corazza, Chan and Roman-Urrestarazu analyses how the rapid diffusion of NPS presents unprecedented legislative and policy challenges to the current drug control regimes and national legislation. It provides a comparative assessment of the current legislative responses to NPS while providing new insights on the potential of a functional-based legal approach in the regulated market, modelled after the UK Human Medicines Regulations 2012. The overall analysis focuses on examining how current legal and policy responses have failed to respond to the NPS challenge and advancing more 'functionalist' legislative solutions to the NPS challenge as an alternative to existing prohibitionist framework based on a wide notion of psychoactivity. It argues how a deficient legal definition of NPS combined with *reactive* legal responses contributes to unintended health and criminal consequences and the diffusion of NPS in the more hidden deep and dark web. It concludes in favour of more accountable regulatory regimes able to accommodate the rapidly changing lifestyles, where drug consumption has moved beyond the traditional recreational use into the realm of 'self-medication', which could be supported by a specialized NPS authority.

The contribution by Martz presents a unique perspective from a DEA intelligence analyst on NPS as major players in the US drug market. While interpreting national data, he argues how legacy indicators do not always scale well to new substances, like NPS. He presents the challenges faced by an analyst when

analysing death, overdose, seizure and identifier data for NPS. He concludes how this must not be interpreted superficially, but requires an interdisciplinary approach.

The contribution by Colson explores how a significant element in the field of the European Union member states' judicial cooperation is the harmonization of their laws. This issue is described as one of the most important aspects of drug policy cooperation between the member states. It then exposes how for almost 30 years Europe has tried to improve its common activities with regard to cooperation in criminal matters by, inter alia, the harmonization of penal laws. This analysis presents the development and current state of the cooperation in regard to NPS legislation within the EU. The author discusses the background and history of the cooperation between the member states in NPS regulation and current legislative efforts in this matter. The work uses a European governance framework that establishes supranational regulatory focus for this emergent public health threat. The author also evaluates the effectiveness of the European supranational response and discusses the evidence and consequences that this regulatory framework has produced in the NPS market.

The contribution by Reuter and Pardo explores the key thematic areas outlined in the book. An accurate comparative policy approach takes a look at evidence-based policymaking in NPS, which has so far been scarce. The novelty of NPS together with the lack of conclusive data on its risks and consequences provides the impetus for this work and discusses this crucial aspect carefully. The authors advocate for the need to have sound empirical evidence and information sharing as a basis to inform better policy responses.

This book is a humble attempt at shedding new light on the ever-changing drug scenario that aims to include and expand upon novel policy solutions to hopefully help facilitate regulatory responses to NPS. We strongly believe this is the right time to be investing joint multidisciplinary efforts into the development of concrete innovative policy responses to NPS as well as a unique opportunity to rethink evidence-based drug policy and legislation as a whole. Finally, we would like to encourage the ability to overcome the fear of change in current approaches and ways of debating NPS. We still do not know what the next challenge after the NPS phenomenon will be, but we cannot be unprepared to face the future.

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