

Submission to the UN Committee on Economic, Social and Cultural Rights on the Right to Enjoy the Benefits of Scientific Progress

cescr-science@ohchr.org

5 October 2018

Harm Reduction International welcomes the invitation to make a written submission in support of the UN Committee on Economic, Social and Cultural Rights' day of general discussion on article 15 of the International Covenant on Economic, Social and Cultural Rights on the right to enjoy the benefits of scientific progress and its applications ('right to science'); and welcomes the consultative process in the context of the drafting of a general comment on the relevant provisions of article 15.

Harm Reduction International works to reduce the negative health, social and human rights impacts of drug use and drug policy – such as the increased vulnerability to HIV and hepatitis infection among people who inject drugs – by promoting evidence-based public health policies and practices, and human rights based approaches to drug policy.

We are motivated to make this submission on the basis of our experience in the harm reduction and drug policy sector, where we continually observe tension related to the evidence and/or the science associated with the response to drugs; and consider that a more detailed elaboration of the right to science will be a critical tool in our work to ensure drug policy is both evidence-based and human rights based.

This submission will focus on Discussion Paper paragraph 35 which speak to the intersection between the international drug control convention, scientific research and access to controlled medicines.¹ **We seek to emphasise how the right to science may enable us to better resolve two key concerns related to harm reduction and drug policy:**

- The limitations imposed by drug control on research into controlled substances.
- The ideological resistance to 'harm reduction' as a concept, notwithstanding the evidence in support of harm reduction interventions; as well as components of harm reduction, in particular opiate substitution therapy.

The limitations imposed by drug control on research into controlled substances²

The drug control conventions are frequently interpreted to maximize control over substances, including research into controlled substances. Scientists in many countries are extremely limited in their ability to undertake (laboratory-based) study into the potential harms or medicinal benefits of controlled substances. Specifically, heavy administrative and bureaucratic regulation of controlled substances (under the auspices of anti-diversion measures) impede lines of inquiry or exceed institutional administrative/financial capacity. This restrictive approach limits the scope and implementation of scientific inquiry to the extent that the drug policy sector is currently decades behind truly understanding the potential medical value and harms of controlled substances. An additional concern is the fact that the narrative of control politicizes the issue of controlled substances and/or enables bias in decision making around scientific review and funding.

We appreciate the conclusions and proposals for the normative framing of the right to science, captured in the Venice Statement, which emphasized freedom of inquiry as a vital element in the development of science, access to the benefits of scientific progress, and the "creation of an enabling and participatory environment for the conservation, development and diffusion of science and technology" as core components of the right to science.³

We further note the comments of the Special Rapporteur in the field of cultural rights, who stipulated that a prerequisite for implementing the right to science is "ensuring the necessary conditions for everyone to continuously engage in critical thinking about themselves and the world they inhabit, and to have the opportunity and wherewithal to interrogate,

¹ <https://www.ohchr.org/Documents/HRBodies/CESCR/Discussions/2018/discussionpaper.pdf>

² This section of the Harm Reduction International submission relies heavily upon a paper by Burke-Shyne, Csete, Wilson, Fox, Wolfe, and Rasanathan in the Health and Human Rights Journal; the authors agreed to the use of this paper as a means of contributing to this important consultative process (Burke-Shyne, et al, 2017 'How Drug Control Policy and Practice Undermine Access to Controlled Medicines' Health and Human Rights Journal <https://www.hhrjournal.org/2017/05/how-drug-control-policy-and-practice-undermine-access-to-controlled-medicines/>)

³ The Venice Statement on the Right to Enjoy the Benefits of Scientific Progress and its Applications, adopted in July 2009 by a group of experts, para 13. Available at: https://www.aaas.org/sites/default/files/VeniceStatement_July2009.pdf

investigate and contribute new knowledge.”⁴ The Special Rapporteur also set out the normative content of the right to science—to paraphrase: access to knowledge and to the benefits of science without discrimination; opportunities to contribute to the scientific enterprise and freedom indispensable for scientific research; information to enable informed decision-making “after considering both the possible improvements offered by scientific advances and their potential side effects or dangerous usages” as well as participatory decision-making in determining what constitutes “benefits” of scientific progress; and an enabling environment.

The two normative conditions most pertinent in the context of drug policy are access and freedom of inquiry. In terms of access, the innovations essential for a life with dignity should be accessible to everyone, in particular marginalized populations. In terms of freedom of inquiry, freedom of scientific research has been interpreted as the right or freedom to assess and choose the preferred path of scientific and technological development.⁵

The Special Rapporteur on cultural rights clarifies that freedom “means ensuring that the scientific enterprise remains free of political and other interference, while guaranteeing the highest standards of ethical safeguards” and explicitly notes that barriers to scientific research must be overcome.⁶

For this reason, we ask the Committee to consider emphasizing the negative obligation under ICESCR Article 15(3), which provides that states must respect the freedom indispensable for scientific research – namely that the state is obliged not to interfere with choices and priorities decided by scientists and not to impose a certain topic or method of research on the academic community.⁷ We recognize that scientific freedom is not absolute, “but centers on the nexus of freedom and responsibility.”⁸ Any restriction to the right to science must comply with the relevant legal standard.

Article 4 of ICESCR provides that rights in that covenant can only be restricted in a manner that is according to law, consistent with the nature of the right, pursuant to a legitimate aim (such as the protection of public health), and strictly necessary for the promotion of general welfare in a democratic society. We believe CESCR’s remarks in General Comment 14 are applicable here, i.e. that “such limitations must be proportional, i.e. the least restrictive alternative must be adopted where several types of limitations are available.”⁹

We provide the following case studies to highlight how the right to science may be applied to great use in the context of research in the drug policy and harm reduction sectors:

1. In the UK, researchers require a special license in order to hold Schedule 1 controlled substances (those subject to the most stringent level of control). Obtaining such a license may take up to one year, cost GBP3000 (plus an additional GBP2000 for security equipment and police checks), and furthermore may require additional import licenses, since most suppliers of controlled substances are located outside the UK. David Nutt, psychiatrist and neuropsychopharmacologist, estimates that overcoming these hurdles increases the cost of the research into controlled substances “by about 10-fold.”¹⁰ Consequently, just four hospitals in the UK hold a Schedule 1 dispensing license. As such, research into the medical value of Schedule 1 substances is effectively smothered, closing opportunities for discovery of therapeutic benefit (or harm).

By way of further illustration, despite initial case reports suggesting a medical value for MDMA analogues (similar in structure to MDMA) in alleviating dyskinesia (involuntary movements) associated with Parkinson’s disease, media hype around potential misuse of MDMA analogues resulted in their blanket classification as Schedule 1 substances.¹¹ This effectively criminalized both the analogues and the research, as the sites conducting the research could not afford Schedule 1 licenses.¹²

⁴ Farida Shaheed, UN Special Rapporteur in the Field of Cultural Rights, *The Right to Enjoy the Benefits of Scientific Progress and its Applications*, UN Doc. A/HRC/20/26 (2012); AAAS Science and Human Rights Coalition, *Defining the Right to Enjoy the Benefits of Scientific Progress and its Applications: American Scientists’ Perspectives* (New York, AAAS, 2013). Available at: http://www.aaas.org/sites/default/files/content_files/UNReportAAAS.pdf

⁵ Y. Donders, “The right to benefit from scientific progress: in search of state obligations in relation to health,” *Medicine, Health Care and Philosophy*, 14 (2011), p. 376

⁶ Farida Shaheed, UN Special Rapporteur in the Field of Cultural Rights, *The Right to Enjoy the Benefits of Scientific Progress and its Applications*, UN Doc. A/HRC/20/26 (2012)

⁷ Y. Donders, “The right to benefit from scientific progress: in search of state obligations in relation to health,” *Medicine, Health Care and Philosophy*, 14 (2011), p. 376; Note also, that the travaux préparatoires show that in proposing the REBSP in 1951, the United Nations Educational, Scientific and Cultural Organization (UNESCO) placed significant emphasis on health and on the realization of other human rights, stating that “scientific discoveries in the theoretical field might lead, especially in the present era, to practical applications of cardinal importance for the improvement of human welfare, more particularly in health.” It added that, “[t]he right of everyone to enjoy his share of the benefits of science was to a great extent the determining factor for the exercise by mankind as a whole of many other rights.” Commission on Human Rights, Summary Record of the 228th Meeting held at the Palais Des Nations Geneva, UN Doc. No. E/CN.4/SR.228, (1951)

⁸ AAAS Science and Human Rights Coalition, *Defining the Right to Enjoy the Benefits of Scientific Progress and its Applications: American Scientists’ Perspectives* (New York, AAAS, 2013). Available at: http://www.aaas.org/sites/default/files/content_files/UNReportAAAS.pdf

⁹ General Comment 14 (see note 15) para 28-29

¹⁰ D.J. Nutt, “Illegal drugs laws: Clearing a 50-year-old obstacle to research,” *PLoS Biology*, 13(1) (2015), p4.

¹¹ P.H. Huot, T.H. Johnston, K.D. Lewis et al., “Characterization of 3,4-Methylenedioxymethamphetamine (MDMA) Enantiomers In Vitro and in the MPTP-Lesioned Primate: R-MDMA Reduces Severity of Dyskinesia, Whereas S-MDMA Extends Duration of ON-Time,” *Journal of Neuroscience*, 31 (2011), pp. 7190–7198.

¹² D.J. Nutt, L.A. King, and D.E. Nichols, “New victims of current drug laws,” *Nature Review Neuroscience*, 14 (2013) p. 877.

Similarly, in Canada, it took a research group sponsored by the Multidisciplinary Association for Psychedelic Studies more than four years to be permitted to import MDMA from Switzerland under a special license, even though the group had already obtained approval from the federal department of health and a Canadian institutional review board to conduct research into the therapeutic use of MDMA in post-traumatic stress disorder.¹³ Nutt notes there are no known instances of diversion of Schedule 1 or Schedule 2 drugs from research labs, “So the law simply censors research rather than protects the public; indeed the limitation to clinical research produced by the regulations almost certainly has done much more harm than good to society by impeding medical progress.”¹⁴

2. The issue of access to cannabis for medical treatment received a high degree of attention in the US after a series of television documentaries on the beneficial effects of a cannabis derivative for children with Dravet syndrome, or treatment-resistant epilepsies, among other conditions.¹⁵ Dr. Sanjay Gupta, CNN’s chief medical correspondent, documented the story of more than 100 American families who moved to Colorado (which authorized patients and their caregivers to possess, cultivate, and use cannabis for medical purposes in 2000), in order to secure regular access to the substance for medical use for their children. As the law currently stands, these patients and families must stay in Colorado, because transporting their medicine (a non-psychoactive cannabis oil) puts them at risk of criminal prosecution. Previously, therapeutic benefits of the cannabis extract had not been scientifically evaluated. Critics of overregulation note that this was the result of restrictions on research with cannabis and its derivatives in the US, including licensing restrictions and refusal to reschedule cannabis by the Drug Enforcement Agency, which retained authority of the decision despite lack of health expertise. These restrictions violate both freedom of inquiry and the requirement for non-discriminatory access to the benefits of scientific progress.
3. LSD is another case in point. Notwithstanding accounts suggesting that LSD may have considerable therapeutic value for treating alcoholism in some patients, researching the medical value of LSD in Europe is made impossible by the fact that there is no approved source of LSD formulation for human clinical trials.¹⁶ In this case, marginalized members of European society—people in need of treatment for alcoholism—are denied access to the benefits of research.
4. In the US, researchers published multiple papers noting that MDMA caused dopaminergic brain damage. The finding was widely circulated, and retracted only after it was revealed that the researchers had mistakenly used methamphetamine—known to impair dopamine function—rather than MDMA, in the experiment. Widespread media coverage of the erroneous finding, along with a lack of appropriate scrutiny of results or interest in replicability, reflects the presumptive prejudice and bias toward detection of harm built into research on psychoactive substances.¹⁷

Restrictions on the exercise of the right to science such as these need to be carefully considered in light of the permissible limitations of rights outlined in Article 4 of ICESCR. Specifically, they should be reviewed to consider whether they are the least restrictive measures in pursuit of a legitimate aim (protection of public health). Given, for example, that the risk of diversion from research laboratories is extremely low, the calculation of proportionality in assessing these restrictions on research should also consider the lost possibility for treatment and medical benefit resulting from drug restrictions. In these circumstances, we argue that draconian restrictions on the right to science, which have a potentially significant impact on the right to health and which seek to combat a small risk of diversion, are often disproportionate and therefore in violation of ICESCR.

Finally, the bias against psychoactive substances also requires attention to the questions *not* asked or comparisons *not* conducted in scientific research. For example, the trial used to approve long-acting naltrexone, an opioid blocker for addiction treatment, compared this medicine to placebo and counseling alone (shown to be inferior to existing treatments in multiple previous studies) rather than to opioids with known medical benefit (and psychoactive effect) used in addiction treatment.¹⁸ Ethicists and researchers have flagged this lapse, and a genuine comparison is now underway

¹³ D.J. Nutt, L.A. King, and D.E. Nichols, “Effects of Schedule I drug laws on neuroscience research and treatment innovation,” *Nature Reviews, Neuroscience*, 14 (2013), p. 580. Available at: <http://www.nature.com/nrn/journal/v14/n8/full/nrn3530.htm>.

¹⁴ Nutt, 2015

¹⁵ S. Gupta, “I am doubling down on medical marijuana,” *CNN International Edition* (March 6, 2014). Available at: <http://www.cnn.com/2014/03/05/health/gupta-medical-marijuana/>; B.E. Porter and C. Jacobson, “Report of a parent survey of cannabidiol-enriched cannabis use in pediatric treatment-resistant epilepsy,” *Epilepsy & Behavior*, 29/3 2013, pp. 574–577.

¹⁶ T. Krebs and P.-Ø. Johansen, “Lysergic acid diethylamide (LSD) for alcoholism: a meta-analysis of controlled trials,” *Journal of Psychopharmacology*, 26 (2012), pp. 994–1002; Nutt (2015, see note 60), p. 3; *Good Manufacturing Practice production, Regulation* (EU) No. 536/2014 of the European Parliament and of the Council on clinical trials on medicinal products for human use and repealing Directive 2001/20/EC, 16 April 2014. Available at: <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014R0536&from=EN>.

¹⁷ G.A. Ricaurte, J. Yuan, G. Hatzidimitriou, et al., “Severe dopaminergic neurotoxicity in primates after a common recreational dose regimen of MDMA (ecstasy),” *Science* 297 (2002), pp. 2260–2263; retraction *Science* 301 (2003), p. 1479; Nutt (2013, see note 83) p. 583.

¹⁸ D. Wolfe, M.P. Carrieri, N. Dasgupta, et al., “Concerns about injectable naltrexone for opioid dependence,” *The Lancet*, 377/9776 (2011), pp. 1468-1470;

between the opioid blocker and the medicines which comprise the gold standard of care.¹⁹ Scientific gaps caused by bias threaten the right to science by undermining the balance of freedom and responsibility in research.

The ideological resistance to ‘harm reduction’ as a concept, notwithstanding the evidence in support of harm reduction interventions; as well as components of harm reduction, in particular opiate substitution therapy

Harm reduction refers to policies, programmes and practices that aim to minimise any negative health, social and economic consequences associated with drug use, drug policies and drug laws. Harm reduction is about meeting people where they are at without judgement, coercion, discrimination or requiring that they stop using drugs, and working with them to bring about positive incremental change in their lives.

Harm reduction encompasses a full range of health and social services and practices that apply to illicit and licit drugs. These services include, but are not limited to, drug consumption rooms, needle and syringe programmes, non-abstinence-based housing and employment initiatives, drug checking, overdose prevention and reversal, and the provision of information on safer drug use. Approaches such as these are cost effective, evidence-based and have a positive impact on individual and community health.

We observe many examples of countries’ efforts to prevent non-medical use of controlled substances dominating drug policy to the exclusion of all other matters. This has the practical impact of undermining harm reduction and undermining access to controlled medicines, including medicines for the treatment of drug dependence, thus infringing upon the right to health. We further observe that the implementation of the scheduling system tends not to be grounded in evidence. In most cases, controlled substances are randomly allocated to schedules which allegedly grade the substances’ medicinal value or potential for harm.

We note the concept of harm reduction is one of considerable political sensitivity in countries which prioritise abstinence from drugs over all other factors. This is also evident at international level, where, in the case of consensus-based decision making we regularly observe strict avoidance of the term ‘harm reduction.’ A key example lies in the Outcome Document from the 2016 UN General Assembly Special Session on the World Drug Problem, which refers to promoting the “elements for the prevention and treatment of drug overdose, in particular opioid overdose, including the use of opioid receptor antagonists such as naloxone to reduce drug-related mortality” – but not ‘harm reduction.’

We raise these issue in the context of this submission because they represents the rejection of scientific evidence on the grounds of ideology. Harm reduction measures, within the definition we endorse, include elements of debate, demonstration and replicability, falsifiability, testability or intersubjective verification or objective refutation.

Harm reduction is critical part of the right to health (as recognised by the Special Rapporteur on the Right to Health).²⁰ Accordingly, it would be particularly important for the Committee to elaborate upon the connection between the rights to science and the right to health; which we see as interrelated and interdependent. In addition, we believe the Committee’s consideration of science should include elements of debate, demonstration and replicability, falsifiability, testability or intersubjective verification or objective refutation (as proposed in Discussion Paper paragraph 15).

Additional notes

With reference to Discussion Paper paragraph 30 (The Scientific Advisory Board of the United Nations /investment), that Harm Reduction International believes the practical implementation of, and realisation of rights is always, in some part, subject to budgetary commitments and budgetary constraints. For this reason, we would strongly encourage the Committee to make comment on the progressive financial commitments which must accompany states’ progressive realization of rights.

¹⁹ E.V. Nunes, J.D. Lee, D. Sisti, et al., “Ethical and clinical safety considerations in the design of an effectiveness trial: A comparison of buprenorphine versus naltrexone treatment for opioid dependence,” *Contemporary Clinical Trials* 51 (2016) pp. 34-43.

²⁰ <http://undocs.org/A/65/255>