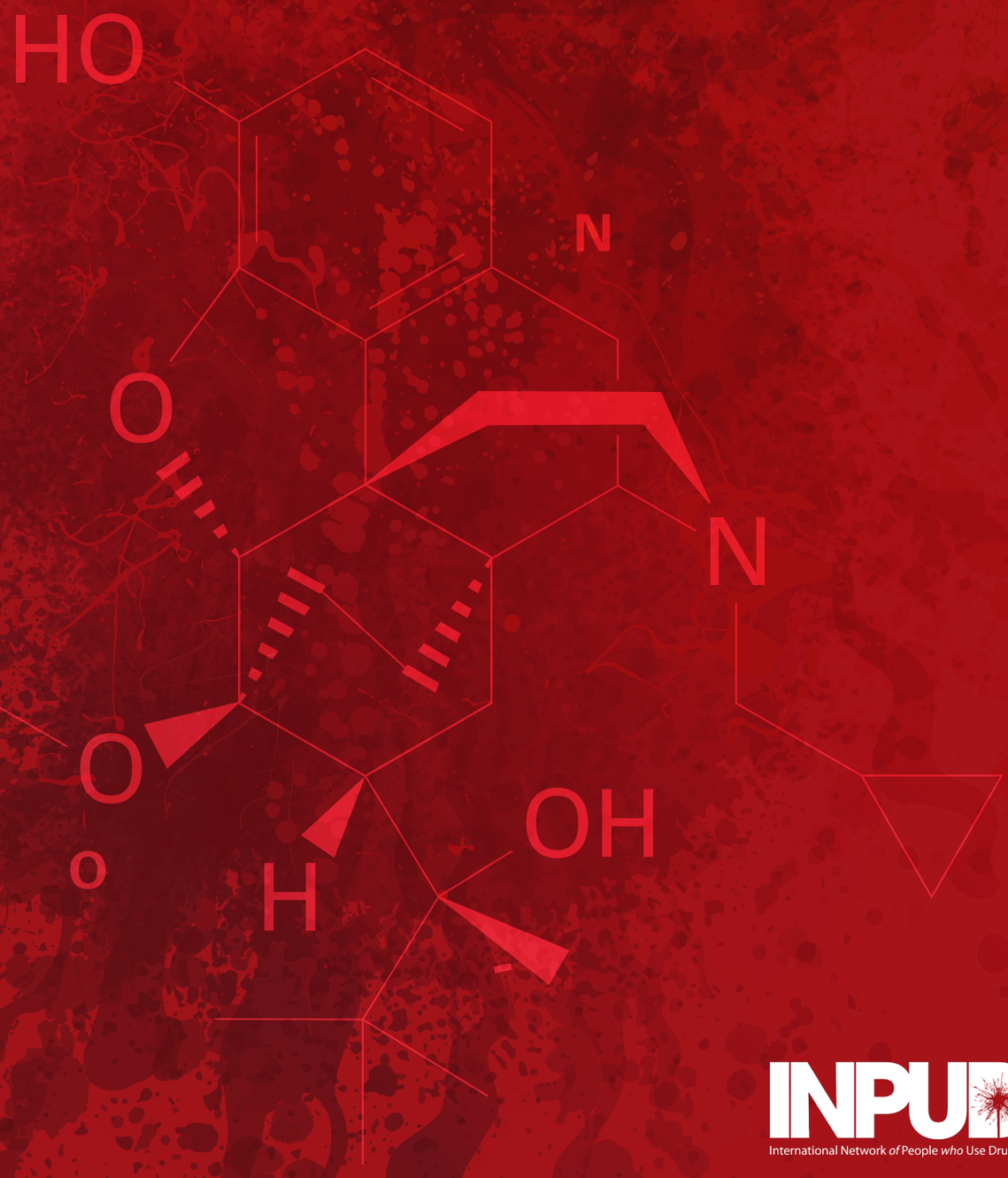
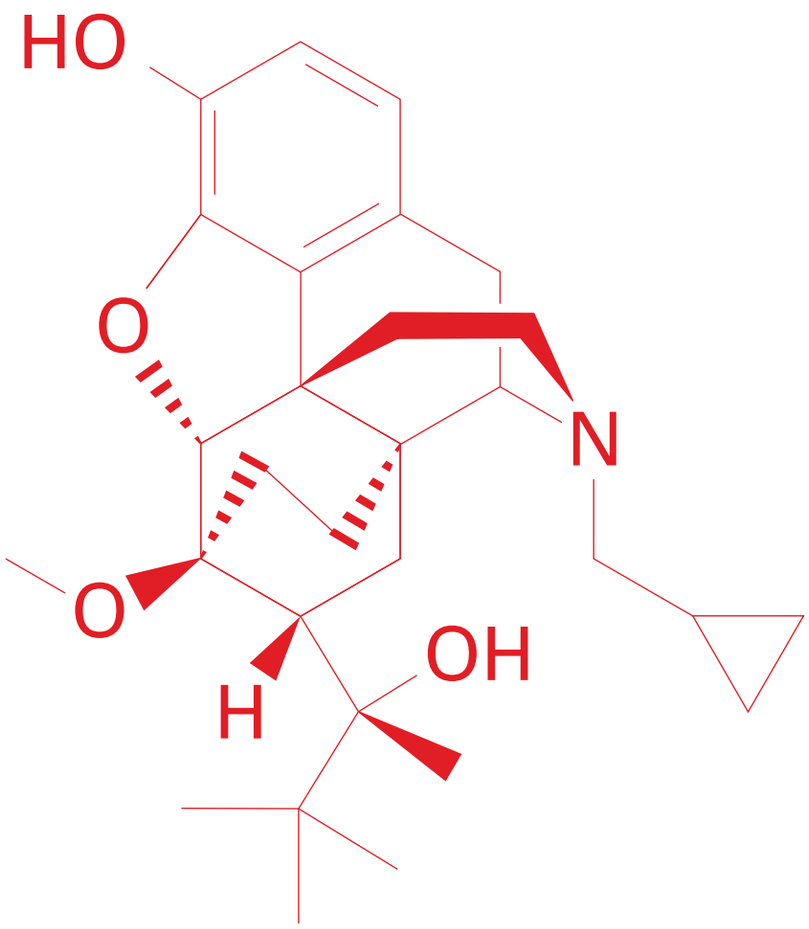
Extended-Release Opioid Agonist Products

A Community Position Statement



INPUD
International Network *of* People *who* Use Drugs



Above: *Chemical structure of buprenorphine*

Introduction

In recent years, services and options for people with opiate dependence have expanded to include a range of prolonged-release buprenorphine formulations. Although these new options can represent the right solution for some individuals, a significant risk of a coercive use exists, especially in countries where people who use drugs are highly criminalised and discriminated against. In such contexts, these medications could be used as a means to reduce people's choice with regard to their bodily integrity and their drug use. In return, this could essentially enforce prohibition and morally-driven ideas of abstinence.

This paper outlines the position of the International Network of People who Use Drugs (INPUD), developed after extensive research and in consultation with people who use drugs and our allies.

Background

"… over-regulation by healthcare and service providers is due to stigma and misguided assertions..."

Opioid agonist therapy (OAT) involves the prescription of opioids, such as methadone, buprenorphine, diamorphine (heroin) or hydromorphone, to people using heroin or other opioids without prescription. OAT is a critical component of harm reduction and is well-demonstrated to reduce incidence and prevalence of blood-borne infections like HIV, hepatitis C, and other infections among people who inject drugs.[1]

Many systematic reviews, randomised trials, and large-scale observational studies[2,3,4] have found OAT programmes to be effective in reducing harms that can be associated with drug use. These programmes have demonstrated an increase in social inclusion and wellbeing, which are associated with a reduction in criminal offenses committed in order to acquire drugs that individuals depend upon. In general, they also improve health and reduce blood-borne infection transmissions. This is all in addition to reducing opiate overdoses, and overdose mortality,[5] both in the community and in closed settings.

Current regulations and practices in the way that OAT is provided can often be overly taxing and burdensome. This negatively impacts access and quality. Programmes often require daily attendance, mandatory urine testing, and long waiting lists. Not to mention, they also place strict limits of take home doses, prioritising concerns of abstinence over improved quality of life. Such over-regulation by healthcare and service providers is due to stigma and misguided assertions that people who use drugs are unreliable and/or non-compliant when it comes to adherence, and these are often used as an excuse.

Advocates have argued about moving away from this model — which is arguably disciplinarian, controlling, undermining of the agency and autonomy of people who use drugs, and interruptive of social and work structure — in favour of a

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[1] From "Substitution maintenance therapy in the management of opioid dependence and HIV/AIDS prevention: position paper" by World Health Organization, United Nations Office on Drugs and Crime, and UNAIDS, 2004. Copyright 2004 by World Health Organization, United Nations Office on Drugs and Crime, and UNAIDS. Reprinted with permission.

[2] From "A Systematic Review of Observational Studies on Treatment of Opioid Dependence", by Bargagli A., Davoli M., Minozzi S., Vecchi S., and Perucci C., 2007, Geneva, Switzerland: World Health Organization. Copyright 2007 by World Health Organization. Reprinted with permission.

[3] From "Methadone maintenance therapy versus no opioid replacement therapy for opioid dependence", by Mattick R.P., Breen C., Kimber J., and Davoli M., 2002, Cochrane Database of Systematic Reviews, 3. Copyright 2002 by Mattick R.P., Breen C., Kimber J., and Davoli M. Reprinted with permission.

[4] From "Mortality among people who inject drugs: a systematic review and meta-analysis", by Mathers B.M., Degenhardt L., Bucello C., Lemon J., Wiessing L., Hickman M., 2013, Bull World Health Organ. 91(2), p. 102-23. Copyright 2013 by Mathers B.M., Degenhardt L., Bucello C., Lemon J., Wiessing L., Hickman M. Reprinted with permission.

[5] From "Methadone maintenance therapy versus no opioid replacement therapy for opioid dependence" by Mattick R.P., Breen C., Kimber J., Davoli M. 2009 by Cochrane Database of Systematic Reviews, Issue 3. Art. No.: CD002209.

more collaborative and empowering solution. A myopic focus on adherence fails to understand both the contexts in which people who use drugs live and the patterns of drug use. Harm reduction programmes and services must adapt to the lived realities of people who use drugs, not shoehorn people into unrealistic and inflexible structures, mechanisms, and practices.

Multiple studies have shown that rights-based approaches that recognise the agency and autonomy of people who use drugs — instead of one's status as people who use drugs — which promote empowerment and non-judgmental relationships between people who use drugs and health care providers are in fact the most reliable direct predictors of adherence.[6] All services and healthcare provision for people who use drugs are most effective when they are delivered in the context of a dynamic partnership between healthcare providers and people who use drugs, tailored to the diverse needs of the individual, as opposed to the 'one size fits all' approach.

In recent years, services and options for people with opiate dependence have expanded to include a range of prolonged-release (also known as extended-release) weekly, monthly, and six-monthly buprenorphine formulations. These new formulations are claimed by their proponents — notably pharmaceutical companies and physicians — as a solution to issues surrounding adherence, improving the convenience of people who use drugs, and preventing diversion. In Europe, the first prolonged-release opiates (weekly and monthly buprenorphine depot injections) were licensed for use in November 2018.[7] In the US, an implantable, six-month formulation and a once-monthly injection formulation have been approved and are currently being marketed.

"… serious concerns arise for the potential for these new drugs to be used to coerce people into abstinence while reducing control over bodies"

However, serious concerns arise for the potential for these new drugs to be used to coerce people into abstinence while reducing control over bodies. These are considerable concerns. These medications, in many contexts, could simply be used as a means to reduce people's choice with regard to their bodily integrity and their drug use, essentially enforcing prohibition and morally-driven ideas of abstinence. Ensuring access to OAT for people who use drugs must be concerned with reducing personal harms and supporting people in self-regulating their drug use, rather than myopically focused on abstinence and punishing people for continued drug consumption.

INPUD's concerns are reflected by the community: in qualitative studies amongst

[6] From "Adherence to HIV Medications: Utility of the Theory of Self-Determination", by Kennedy S., Goggin K., and Nollen N., 2004, Cognitive Therapy and Research, 28 (5), p. 611-628. Copyright Kennedy S., Goggin K., and Nollen N. Copyright 2004 by Kennedy S., Goggin K., and Nollen N. Reprinted with permission.

[7] From "Buvidal®" by European Medicines Agency, 2019. Copyright 1995-2019 by European Medicines Agency. For more information refer to https://www.ema.europa.eu/en/medicines/human/EPAR/buvidal.

Community Perspectives

"...participants expressed fears about the potential of these formulations to be used to enforce coercive treatment..."

people who use drugs,[8,9] participants expressed fears about the potential of these formulations to be used to enforce coercive treatment, leading to reduced choice and control of their lives. A meeting of 14 representatives of drug user rights organisations from 9 European countries raised the same concerns, emphasising concerns about the potential of misuse of depot buprenorphine by prescribing doctors to impose abstinence on people who use drugs. Indeed, these concerns extended to the impacts such drugs could have on harm reduction packages and services, as these long-acting formulations cost exponentially higher than daily doses (up to $1800 per month compared with 7 dollars for methadone[10]). In place, more ethical, practical, and affordable options could be supplanted. Participants also flagged the risk that decisions on who should use these devices could be based on prejudice and assumptions about the inability to adhere to a treatment, which is often driven by misguided and stigmatising generalisation, drug-user phobia, and intersected by racism and classism.

Such controlling policies, applied through the lens of medical science, are nothing new. INPUD has previously emphasised that people who use drugs, notably women, and people of colour, have been violently controlled and socially excluded. Since women who use drugs are often viewed as unfit mothers, they have been forced and/or coerced into terminating pregnancies, as well as into giving up their children and being sterilised.[11] Birth control had been historically used among populations of women seen to be 'unfit' to socially engineer, delimit, and control their procreation.[12] In a similar show of state control over the bodies' of marginalised communities, long-acting naltrexone, an opioid blocker, have been marketed to and widely used primarily in the prison system, essentially enforcing a prohibition *inside* the bodies of people who use drugs, creating bodies that *cannot* be psychoactively affected by drugs of choice.

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[8] From "Implants and depot injections for treating opioid dependence: Qualitative study of people who use or have used heroin", by Neale J., Tompkins C.N.E, McDonald R., and Strang J., 2018, Drug Alcohol Depend, 189, p. 1-7. Copyright 2018 Neale J., Tompkins C.N.E, McDonald R., and Strang J. by Reprinted with permission.

[9] From "Prolonged-release opioid agonist therapy: qualitative study exploring patients' views of 1-week, 1-month, and 6-month buprenorphine formulations" by Neale J., Tompkins C.N.E., and Strang J., 2019, Harm Reduction Journal, 16 (25). Copyright 2019 by by Neale J., Tompkins C.N.E., and Strang J. Reprinted with permission.

[10] From "Methadone maintenance and the cost and utilization of health care among individuals dependent on opioids in a commercial health plan" by McCarty, D., Perrin, N. A., Green, C. A., Polen, M. R., Leo, M. C., & Lynch, F. 2010, Drug and alcohol dependence, 111(3), p. 235-240. Copyright 2010 by McCarty, D., Perrin, N. A., Green, C. A., Polen, M. R., Leo, M. C., & Lynch, F. Reprinted with permission.

[11] From "Contraception, punishment and women who use drugs" by Olsen, A., Banwell, C., & Madden, A., 2014, BMC Women's Health, 14, p. 5. Copyright 2014 by Olsen, A., Banwell, C., & Madden, A. Reprinted with permission.

[12] From "The History and Politics of Birth Control" by Fee, E., & Wallace, M., 1979, Feminist Studies, 5(1), p. 201-215. Copyright 1979 by Fee, E., & Wallace, M. Reprinted with permission.

We must emphasise that all long-acting formulations that require invasive procedures that prevent people from self-regulating their daily intake (as for injectable buprenorphine) or require a doctor to remove implants (as for naltrexone) are inherently coercive. These concerns must be engaged with and discussed with considerable care, caution, and nuance. Other concerns include excessive pricing that might divert resources from cheaper and more manageable daily doses and harm reduction services.

As much as these long-acting formulations *can* represent a welcome additional option for people who use drugs and have drug dependencies to improve our quality of life — if chosen and taken in a context of unbridled informed consent — they also carry a considerable risk of coercion. In such cases, they undermine the agency and autonomy of people who use drugs, and divert time and resources from cost-effective, well-proven interventions.

In short, what are claimed to provide greater choice for people who use drugs can easily become instruments of control and a form of reduced choice, when the choice is taken away from people who use drugs where spurious goals of abstinence are the main criteria in deciding the best treatment.

Moving forward: the pros and cons

"… most frequently harassed by the police are those who are most disenfranchised…"

Potential benefits

Given the very real concerns surrounding these interventions — in terms of the health and rights of people who use drugs, and the potential for undermining informed consent and bodily integrity of those who prescribed these medications — it is important to emphasise the contexts in which our use would be of benefit. For people on OAT, who want to make their lives more comfortable by reducing their contact with the medical establishment by switching to a once-monthly treatment administration at their GP or pharmacist, these substances allow greater freedom. Similarly, in countries where take-home is not widely available or not at all, these formulations have the potential to remove many of the restrictions around dosing, allowing people to travel without the concern to collect and access regular medications. Additionally, in contexts where frequent travel to clinics is burdensome and difficult — thus providing a barrier to care — these substances would greatly remove such constraints.

Legitimate concerns

Concerns about the potential of depot buprenorphine being used coercively are high amongst the community. For instance, depot buprenorphine could be prescribed by healthcare providers and doctors, as well as in institutions including closed settings, and mandated in judicial settings (e.g., by drug courts) and under punitive conditions (such as a requirement for parole and being released from prison) to impose non-consensual abstinence from illicit opioids over a considerable period of time. These are often done, irrespective of whether an individual changes their mind with regard to our desire to use or not to use drugs. Given the opioid blocking effect of buprenorphine and reduced supervision requirements, this particular long-acting formulation is an attractive tool for managers/policymakers seeking to exert greater control over people who use drugs and save money.[13]

In short, depot buprenorphine can be used as a tool for control and coercion. Not only does it undermine a person's ability to choose how and when we use drugs, but these interventions additionally take away a person's ability to self-regulate our use of opiates with regard to desired psychoactive drug effects. Not to mention, it also undermines any ability for us to share our OAT drugs with community members and friends who are otherwise unable to acquire their medication and drugs and do not, for example, want to disclose their drug use to service and healthcare providers.

"… this particular long-acting formulation is an attractive tool for managers/ policymakers seeking to exert greater control over people who use drugs..."

The community of people who use drugs are very concerned that these new formulations will be used to enforce abstinence, and be used as an additional weapon in the arsenal to impose morally-driven ideology on drug use and social control of people who use drugs.

[13] From "Partnership Quality Declaration on Opioid Agonist Therapy position statement" by European Network of People who Use Drugs, 2019, Copyright 2019 by European Network of People who Use Drugs. Reprinted with permission.

Naltrexone implants

"… most frequently harassed by the police are those who are most disenfranchised…"

A different but parallel set of issues concern the use of naltrexone implants. Naltrexone implants are used as abstinence therapy for patients with opioid, alcohol, and to a lesser extent, amphetamine dependence. Naltrexone has been heavily promoted and marketed to the criminal justice system despite its high rates of overdose risk (with a mortality rate four times higher than for methadone and substantially higher than for buprenorphine)[14] as part of a fundamentalist abstinence-based moralistic approach to drug use that led to a spate of overdose deaths in Australia in the late 1990s.

Research has confirmed naltrexone's pharmacological efficacy in blocking the actions of opiates.[15] A relatively few number of clinical studies have also shown it to be as effective as buprenorphine in "deterring" opioid use. As some people who use drugs are not always interested in completely "deterring" our use, many people who have opiate dependencies are reluctant or refuse to take naltrexone. There were also many others who begin but do not continue treatment. Up until now, no long-term studies on naltrexone implants have been done so far.

Marketers and lobbyists often characterise the administration of methadone and buprenorphine as the gold standard for treating opioid dependence. With the naltrexone implants, to them it was "simply replacing a drug with another drug". As a result, sales of naltrexone implants in the US have increased by more than 600 percent since 2011,[16] while multiple jurisdictions have now created mechanisms requiring drug offenders appearing before them to use that medication if they wish to avoid imprisonment. Naltrexone is subject to a limitation applicable to any object — in this case medication — that deprives us of experiences we value in our lives; the more "effective" it is, the more patients simply refuse it or quickly abandon the treatment. This means that the treatment is more likely to be forcibly prescribed for sentenced offenders, who by definition are already coerced into doing things they would not otherwise do.

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[14] From "Mortality related to naltrexone in the treatment of opioid dependence: A comparative analysis" by Gibson A, and Degenhardt L., 2005, NDARC Technical Report, 229. Copyright by National Drug & Alcohol Research Centre, University of New South Wales, Sydney NSW 2052, Australia. Reprinted with permission.

[15] From "Opioid challenge evaluation of blockade by extended-release naltrexone in opioid-abusing adults: dose-effects and time-course" by Bigelow G.E., Preston K.L., Schmittner J., Dong Q., and Gastfriend D.R., 2012, Drug Alcohol Depend, 123 (1-3), p. 57-65. Copyright 2012 by Bigelow G.E., Preston K.L., Schmittner J., Dong Q., and Gastfriend D.R. Reprinted with permission.

[16] From "Pain Management and the Opioid Epidemic: Balancing Societal and Individual Benefits and Risks of Prescription Opioid Use" by Phillips J.K., Ford M.A., Bonnie R.J., 2017, National Academies of Sciences, Engineering, and Medicine; Health and Medicine Division; Board on Health Sciences Policy; Committee on Pain Management and Regulatory Strategies to Address Prescription Opioid Abuse, Washington: National Academies Press. Copyright 2017 by National Academies Press. Reprinted with permission.

Naltrexone implants, through existing as an implanted *part* of a person's body, by default remove agency to manage drug use in the absence of any proven clinical benefit, beyond that of blocking opiate receptors. On the contrary, it increases mortality risk.

Based on these considerations, INPUD has collectively developed the following position:

- Drug treatment is most effective – and is only acceptable – when people who use drugs are empowered, with our agency and self-determination respected as part of a dynamic partnership with healthcare providers. Such person-centred approaches are the only ways of ensuring that services are tailored to individual needs, building on an informed population aware of the range of agonist drugs and good practice in drug treatment.

- While we acknowledge that extended-release opioid agonist products can represent the right solution for some individuals, a significant risk of coercive use exists, especially in countries where people who use drugs are highly criminalised and discriminated against. Long-acting buprenorphine and naltrexone implants, in particular, can constitute a challenge to self-determination, people's agency in managing their drug use, and to evidence-based and human rights compliant drug treatment.

- INPUD will continue to emphasise such risks, while demanding that drug user activists are properly included in the design and evaluation of long-term studies about effectiveness, feasibility, and acceptability of long-acting formulations.

- Aware of the risk of prioritising treatment options that benefit the service provider or the market more than the individual in question, we are in favour of putting the choice in the hands of the client, and making sure that "effectiveness" towards spurious goals of abstinence is not the only or the main criteria used in deciding the best treatment.

The International Network of People who Use Drugs (INPUD) is a global peer-based organisation that seeks to promote the health and defend the rights of people who use drugs. INPUD will expose and challenge stigma, discrimination, and the criminalisation of people who use drugs, and its impact on the drug-using community's health and rights. INPUD will achieve this through processes of empowerment and advocacy at the international level, while supporting empowerment and advocacy at community, national and regional levels. **www.inpud.net**

INPUD is part of Bridging the Gaps – health and rights for key populations. This unique programme addresses the common challenges faced by sex workers, people who use drugs and lesbian, gay, bisexual and transgender people in terms of human rights violations and accessing much-needed HIV and health services. Go to www.hivgaps.org for more information.

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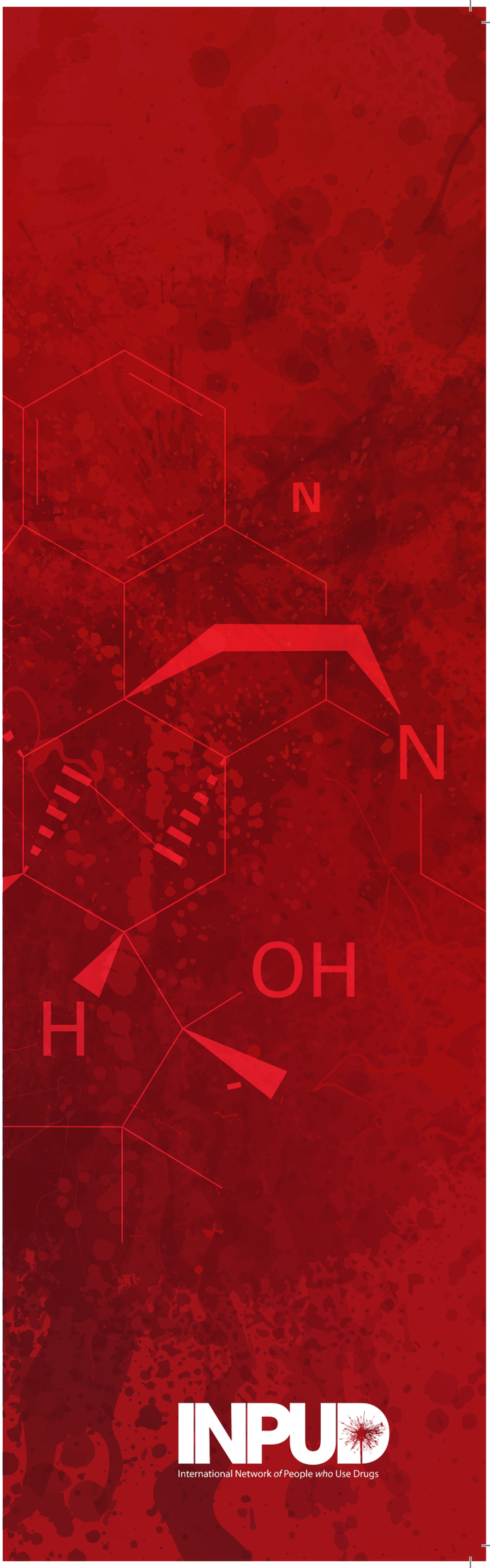

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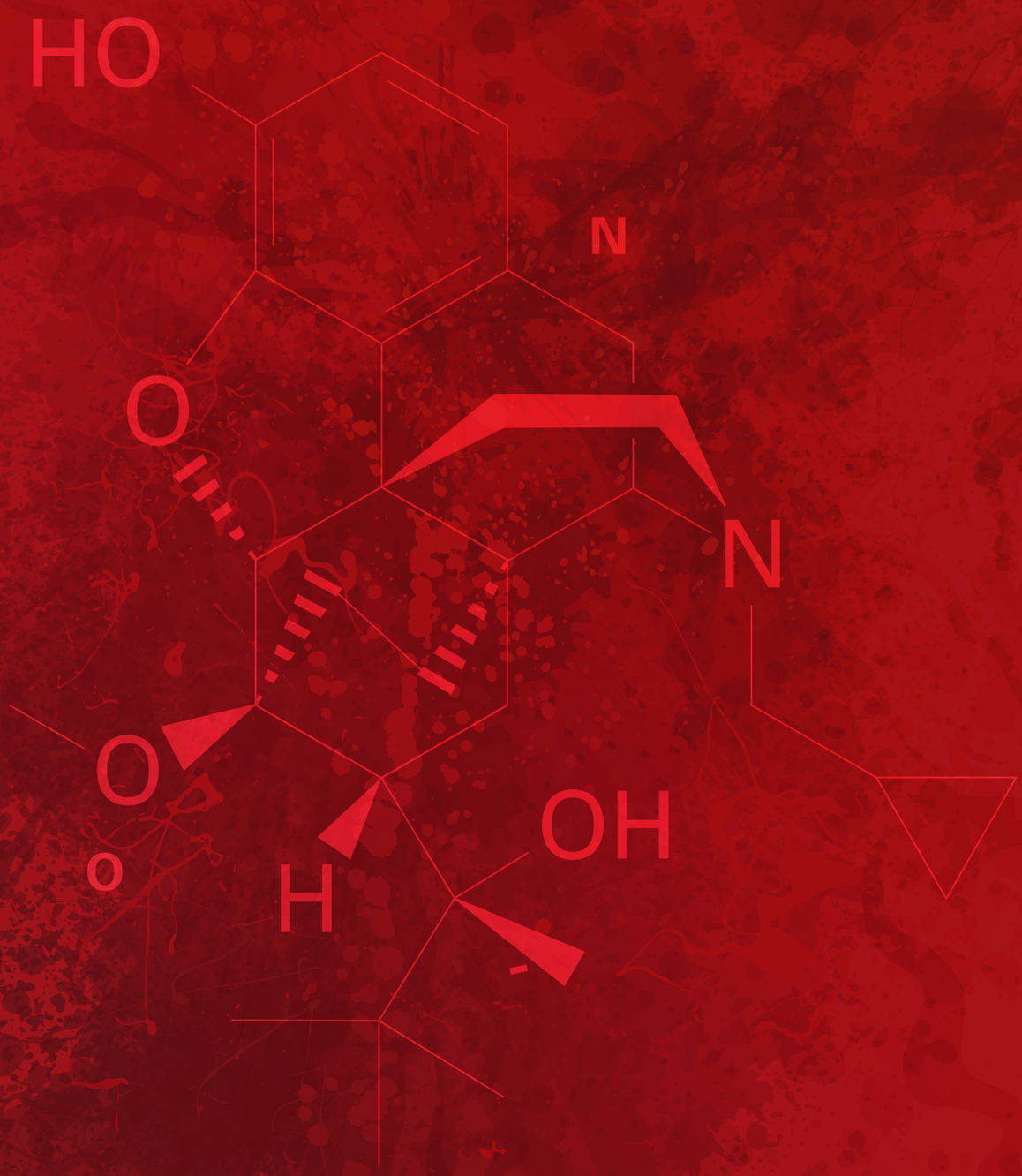

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