ALICE RAP Policy Frame\textsuperscript{1} to reduce the harm done by addictive\textsuperscript{2} drugs and behaviours\textsuperscript{3}

Taking addictive drugs alone, illegal drugs were responsible for 1.4% of all years lost due to ill-health and premature death in the European Union in 2010, alcohol for 5.3% and tobacco for 11.4%, imposing economic burdens in excess of 2.5% of GDP\textsuperscript{4}. The ALICE RAP project (http://www.alicera.eu/) is a €10 million, five-year (2011-2016) action co-financed by the FP7 programme of the European Union to study the place of addictions and lifestyles in contemporary Europe. One thousand months of scientific endeavour in disciplines ranging from anthropology to toxicology have analysed the biological, economic, medical, political and social factors behind addictive drugs and behaviours. This work has led to this 12-point ALICE RAP Policy Frame to inform a redesign of the governance approaches to reduce the individual and societal harm done by addictive drugs and behaviours.

1. ‘Heavy use over time’ is proposed as the replacement descriptor for concepts and terms such as ‘addiction’ or ‘dependence’. Heavy use over time is the primary determinant and predictor of the health and social sequelae normally captured by terms such as ‘addiction’ and ‘dependence’. Heavy use over time is a more accurate description; it recognizes that use and harm exist within continua with no natural cut-off points; and adopting it could help to reduce the stigma associated with dichotomous labelling (e.g. addict versus non-addict)\textsuperscript{5}. Heavy use over time is responsible for the changes in the brain and other physiological characteristics of addictive disorders; is responsible for intoxication, and for the loss of control characterizing current definitions of addiction; is responsible for the main social consequences of using addictive products, such as problems in fulfilling social roles; is responsible for the majority of burden of disease and mortality attributable to using addictive products; and, as a descriptor, overcomes many of the historical, cultural and political uncertainties and current problems with definitions and operationalization, which vary a great deal between different countries\textsuperscript{6,7}. Transitions into and out of heavy use over time are determined by an interplay of molecular, individual and societal factors\textsuperscript{8}.

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\textsuperscript{2} We do not subscribe to the view that addiction is in itself a disease or condition; rather, we use the word ‘addictive’ as shorthand to encompass a range of drugs (alcohol, nicotine, and illegal psychoactive substances) and behaviours (such as gambling / gaming) whose sustained heavy use over time leads to long-term harm.

\textsuperscript{3} ALICE RAP has studied a range of drugs, including alcohol, nicotine and a number of other legal and illegal psychoactive substances, and one behaviour, gambling. ALICE RAP has not studied in any comprehensive way other substances such as sugar, or other behaviours, such as playing video games and sexual activity.


2. **Policies should acknowledge and aim at reducing the social stigma linked to using addictive drugs and products.** Heavy use of drugs and other addictive products are some of the most stigmatized behaviours over time and place\(^9\). Because it is a powerful social force, stigmatization functions as a barrier to the normalization of advice and treatment for addictive drug use and behaviours that should meet the same standards of care and service provision as for any other chronic condition, such as diabetes or high blood pressure. Further, stigmatization maintains structural inequalities in society. A European coordinated and continued action, involving public, non-governmental and private sectors, should be mobilized to bring about a cultural transformation that reduces the stigma associated with addictive drugs and behaviours and their treatment.

3. **Policies should be based on a sound understanding of evolutionary behaviour.** Ecological analyses find humans have evolved to be active and functional, rather than passive and vulnerable with respect to the drugs that they take. Many drugs are plant neurotoxins\(^10\), and ethanol results from fermenting sugar in fruit\(^11\). Humans have evolved to counter-exploit these drugs for advantage\(^12\). This has at least two implications: first, policies that prohibit the use of drugs are likely to fail because people have a biological predisposition to seek these chemicals; and, second, in modern society, drug potency and related drug delivery systems are a core drivers of harm, with potency largely determined by producer organisations operating in inadequately managed markets\(^13\).

4. **Policies should be assessed for their impact on a range of societal well-being outcomes beyond physical and mental health.** At the international level, the OECD societal well-being frame is a useful conceptual framework for assessing the unintended and unaccounted harm caused by policies\(^14\). Well-being analyses find that, whilst some drug and gambling policies reduce health harms and bring co-benefits, they can simultaneously have adverse side-effects, including criminalization and related violence, social stigma and social exclusion, which detract from individual and societal well-being\(^15\). To minimize these adverse side-effects, drug and gambling policies should account for overall contexts and dimensions of well-being, for example, through relational management strategies. This means policies should be built on a comprehensive structure that involves different stakeholders and processes. Policies should, for instance, balance decriminalization of illegal substances with innovative harm reduction policies; and effectively regulate legal drugs, such as tobacco and alcohol\(^16\), and legal behaviours, such as gambling\(^17\). Regulation, not an unfettered free market at one extreme, or prohibition with its attendant criminalisation at the other extreme, should be at the centre of drug and gambling policies.

5. **Policies should be informed and monitored by quantitative risk assessment.** Quantitative risk assessment is widely applied in other fields for prioritization of risk management actions. For example, the Margin of Exposure (MOE) for any substance gives an indication of whether individuals or populations are exposed to (or

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use) a substance at an acceptable level of risk or not\textsuperscript{18}. The methodology can be applied to any legal or illegal drug, enabling comparisons of MOE between drugs, which can indicate which drug requires a policy shift or amendment. Margins of exposure compare the ratio of a toxic dose of a drug (usually the benchmark dose BMDL\textsubscript{10}, the lowest dose which is 95% certain to cause no more than a 10% negative outcome incidence) with the dose consumed. A MOE of 100 means that the drug is being consumed at one hundredth of the toxic dose; a MOE of 1 means that the drug is being consumed at the toxic dose – thus, the higher the MOE, the lower the level of risk. MOE for drugs can be calculated taking into account a range of hazard outcomes, in health and other well-being domains, so far as suitable dose-response data are available (which is not the case for most drugs). Therefore, analyses to date are primarily restricted to lethal outcomes based on animal studies. These initial analyses suggested that most efforts should go to reducing use of alcohol, nicotine, cocaine and heroin\textsuperscript{19}. With this quantitative risk assessment, drug policies could aim for a MOE of no less than 10 for individual daily consumption of voluntarily consumed drugs\textsuperscript{20}. It is important to note that the MOE as described here applies where the harm from the drug is inherent in the drug itself (e.g. nicotine); it does not account for the harms that arise from drug delivery systems, for example, smoked tobacco that delivers nicotine.

6. Policies should be judged for their impact in reducing heavy use. In general, the risk of harm from addictive drugs and behaviours increases with the dose of the drug taken, or the time involved with the behaviour, along a continuum of risk\textsuperscript{21}. The shapes of risk curves vary, depending on the drug, the behaviours and the harm being measured, between linear risk curves and curvilinear risk curves, where risk increases disproportionally faster at higher doses. The preponderance of curvilinear risk curves leads to the findings that the majority of individual and societal addictive-related harms results from heavy use\textsuperscript{22}; thus, the same reduction in heavier use brings greater individual and societal benefit than the same reduction in lighter use\textsuperscript{23}. This means that policies and actions, including individually directed advice and treatment programmes, will bring greater health gain when they focus on reducing heavier drug use than when they reduce lighter drug use.

7. Drug policies should recognise the vulnerability of the adolescent brain, particularly with respect to decision making abilities. Adolescence is a time of enormous biological and social change accompanied by increased risk taking. During adolescence, the brain undergoes profound structural change until at least about 25 years of age\textsuperscript{24}. During this time, young people have a well-developed reward system but they have a more flexible engagement of the executive control centre than when fully adult, meaning that young people’s skills in controlling impulses and planning behaviour are still being developed\textsuperscript{25}. Adolescent brain development, itself, might be impaired by drug use, which, in turn, renders a young person who uses drugs at greater risk of longer term drug use.\textsuperscript{26} Drug policies should not penalise or stigmatise underage people who use drugs. Younghood should be engaged in the development and implementation of drug policies. Youth-informed policies should focus on reducing early onset or heavy use and reducing the use of high potency or unregulated harmful substances\textsuperscript{27}.

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Policies and actions should aim to reduce risk, build resilience, and promote physical and mental health. Drug policies focussed on youth need to be embedded in whole-of-society and whole-of-government, youth development policies that aim for security of education, employment and full civic engagement. Policies that restrict access to these basic rights for underage people who use drugs are expensive and can lead to greater risk of drug use and harmful use due to secondary effects of social exclusion.

8. **Policies should ensure that the gaps between those who need advice and treatment and those who receive it are overcome.** United Nations Sustainable Development Goal 3 aims to ensure healthy lives and promote well-being for all ages, ([http://www.un.org/sustainabledevelopment/sustainable-development-goals/](http://www.un.org/sustainabledevelopment/sustainable-development-goals/)) with target 3.5, strengthening the prevention and treatment of substance use problems, including narcotic drug use and harmful use of alcohol. A core indicator to monitor achievement of the goal is coverage of treatment interventions (pharmacological, psychosocial and rehabilitation and after care services) for substance use disorders. Presently, there is an unacceptable treatment gap for drugs and addictive behaviours that leads to loss of life and undermines societal well-being. Across Europe, fewer than 1 in 10 people who would benefit from treatment of alcohol use disorder receive any treatment. In the United States, for example, only 13.5% of adults who would benefit from treatment of drug use disorder during the previous twelve months have received treatment. Further, there are also many lost years between the start of substance use disorders and receiving treatment, often referred to as the ‘decade of harm’. Closing the treatment gap would bring health gains, reduce preventable deaths and disability, improve social inclusion, reduce stigma, and can have a positive impact by lessening the human and economic costs currently accrued due to processing drug users through the criminal justice system.

9. **Drug policies should ensure that programmes designed to prevent harm are assessed for their cost-effectiveness by agencies similar to those that assess pharmacological treatments.** Programmes and actions designed to promote health and healthy lifestyles, and to prevent health problems and illnesses, can improve individual and societal health and well-being and give a good return on investment. Yet, many current prevention programmes are poorly evaluated or not evaluated at all. Some programmes actually do harm and should be withdrawn. Through mapping and systematic reviews of reviews, there is little evidence to support the majority of prevention approaches currently adopted and delivered by many European countries to address drug problems. By contrast, prevention efforts can lead to substantial reductions in drug-related harm when evidence-based programmes are implemented. Although some countries have bodies that review the impact of prevention and lifestyle programmes, the existence of such institutions is not consistent or widespread across Europe. In contrast, all countries have mechanisms in place to assess the safety and effectiveness of pharmacological treatments. At the European level, the European Medicines Agency ([http://www.ema.europa.eu/ema/](http://www.ema.europa.eu/ema/)) is responsible for the scientific evaluation of medicines developed by pharmaceutical companies for use in the European Union. Modelled and improving on the European Medicines Agency, prevention and health promotion programmes could be approved by national agencies or a European Prevention Agency, specifically set up for the purpose, and covering all health topics.

10. **Smart policies require whole-of-government and whole-of-society approaches.** The whole-of-government, or joined-up government, approach represents the diffusion of governance vertically across levels of government.

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32 Faggiano, F; Allara, E; Giannotta, F; Molinar, R; Sumnall, H; Wiers, R; Michie, S; Collins, L; Conrod, P. (2014) Europe needs a central, transparent, and evidence-based approval process for behavioural prevention interventions. PLoS medicine, 2014, 11, 10, e1001740.
and areas of governance as well as horizontally throughout sectors, institutions and professions. This approach requires building trust, a common ethic, a cohesive culture and new thinking and skills throughout all parts of government. The approach includes cabinet committees, interministerial or interagency units, intergovernmental councils, task forces, lead agency assignments, cross-sectoral programmes and projects and mechanisms for overseeing policies and convincing agencies to work together. Whole-of-society approaches involve collaborative governance that emphasizes coordination through normative values and building trust and ownership among various actors in society. The whole-of-society approach goes beyond institutions, and influences and mobilizes local and global culture and mass media, and all relevant public and private policy sectors, such as agriculture, education, transport, media and entertainment, justice, and urban design in reducing harmful drug use and behaviour. Whole of government and whole of society approaches need to address the structural factors of poverty and marginalization that are independent determinants of harm, over and above the addictive drugs and behaviours themselves.

11. **Government policy-making for addictive drugs and behaviours should be free of the undue influence from relevant private producer companies.** The potency of business influence on policy-making is too high, and can lead to a weakening of policy at the expense of health. Private producer companies generally wield a great deal of economic, political and organizational power in the policy arena, often fostering common policy interests that are not conducive to health. There are many structural factors to counter private sector influence, one of which includes a redesign of governance systems that shift away from the present short-term, fast-scale economic and political systems in favour of longer time-scale systems that promote sustainable health and well-being. Whole-of-government and whole-of-society approaches to drug policy should define the relation with private sector stakeholders and establish the rules of the game for stakeholder engagement in the policy cycle through accountability for the common good, where private sector stakeholders contribute to the public health good, simultaneously to their own interests. In order to ensure societal well-being is enhanced, rather than in the hands of commercial interests, the leading role in determining the strategy of public policy for drugs should be in public sector hands. Transparency systems, controls on the revolving door and enhanced conflict of interest policies should be put in place in government, science, civil society and the media as drivers to increase the impact of evidence-based information on decision-making. One approach for producer companies to reduce harm is to change the potency of their products (for example, reducing alcohol concentration of existing products) and the toxicity of their drug-delivery systems (for example cigarette companies shifting to electronic nicotine delivery devices). Shifts towards less harmful products could be incentivized by smart government tax policies.

12. **A health footprint can be used as an accountability tool to apportion the harm to health and premature death imposed by the different drivers of addictive drug use and behaviours.** Structural drivers of harm from the use of addictive products and behaviours include biological attributes and functions, population size and structure, and levels of wealth and income disparities within jurisdictions (see figure). Core drivers refer to

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the processes, mechanisms, and characteristics that influence harm, sometimes through the structural drivers, and sometimes not. Core drivers of harm include drug potency and drug exposure levels, the technological developments that might influence these, and social influences and attitudes, including social stigma and social exclusion. Included in the policy drivers level are measures that reduce drug exposure, actions that promote research and development to reduce drug potency, measures that maximize co-benefits and minimize adverse side-effects of policies and actions, incentives for healthy individual behaviour, and legislation aimed at managing markets, such as the definition and enforcement of rules of engagement of the private sector. Policies and measures affect the core drivers of harm. The structural and core drivers may, in turn, influence policies and measures.

**Figure** Drivers of harm done by drugs and addictive behaviour.

Placed at the centre of the drivers is the Health Footprint, the accounting system for identifying the determinants of drug and addictive behaviour-related harm and the management tool to evaluate opportunities by the public and private sectors and civil society to reduce harm. Modelled on the carbon footprint, the health footprint can be defined as a measure of the total amount of risk factor attributable disability adjusted life years (DALYs) of a specific population, sector or action of interest, defined by specific spatial (e.g., jurisdiction) and temporal (e.g. stated year, such as 2014) boundaries. The Health Footprint can measure the impact of a range of structural and core drivers of impaired health, and the policies and measures that impact upon them. The Health Footprint, thus, accounts for who and what causes the harm done by drugs and addictive behaviours. Drug and addictive behaviour-related health footprints could become standard components of annual reporting by relevant public and private sector bodies.