Regulating risks – Framework for a policy of psychoactive product regulation

Discussion paper of the Federal Commission for Issues relating to Addiction and the Prevention of Non-Communicable Diseases (FCAND)

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This report was originally published in German and French under the title "Risken regulieren: Ein Orientierungsrahmen für die Suchtpolitik / Prévenir les risques par la regulation Un cadre d'orientation pour la politique des addictions". These official versions address a Swiss audience – especially Swiss policymakers already familiar with some of the concepts and regulatory tools this report refers to as well as the Swiss political system. The English version of the report has been adapted for an audience not familiar with the Swiss context. It contains paragraphs that do not exist in the official versions and in some instances uses different wording in order to facilitate understanding by non-Swiss readers. The English version is not an official version of the report.

Contents

Summary

The use of psychoactive products inherently entails risks. To control these risks, the State intervenes in their production, advertisement, distribution and consumption. These interventions in the markets for psychoactive products are enacted in regulatory frameworks of varying strictness. Some substances are completely prohibited (e.g. heroin or ecstasy), while the consumption of others is permitted with restrictions (e.g. alcohol or gambling) and others are not restricted at all (e.g. pornography).

The State has attempted to regulate psychoactive products for decades. This report discusses 26 policy instruments – called "regulatory tools" in this report – to do so that have been implemented in Switzerland.

The application of this regulatory toolkit – called "regulatory mix" in this report – varies widely across products. This is mainly the case because the regulation of psychoactive products always happens in a historical and normative context. It is shaped by the zeitgeist, the perceived threats of the product at hand, and the interests of those in power. Viewed across various products, this has resulted in a regulatory "patchwork" that is incoherent and ineffective from a public health perspective, as the Federal Commission for Addiction and Non-Communicable Disease Prevention (FCAND) already noted in its previous report "Regulating Psychoactive Products in Switzerland".

With the current report "Regulating Risks," the FCAND moves beyond problem diagnosis. By proposing to combine the 26 policy instruments in the policy toolkit to regulate psychoactive products in a flexible, risk-sensitive way, it puts forward an overarching framework to regulate the societal risks stemming from psychoactive products. This framework provides policymakers with a systematic basis for making decisions when it comes to the regulation of psychoactive products and their effects on consumers and society more broadly. It draws on scientific evidence and practical experiences to facilitate a discussion that addresses the regulation of these risks in a more objective and more coherent way than is currently happening. In doing so, this report aims to answer three core questions all policies to regulate psychoactive products must address:

Question 1:

Is there a need to regulate a specific psychoactive product?

Not every product should be subject to regulation. From the point of view of the FCAND, in order to comply with constitutional requirements on regulation:

- a product must have psychoactive effects and/or carry a risk of dependency.
- the consumption of this product must entail discernible risks, affecting not only individual consumers but also their social environment as well as society and the economy in a broader sense.
- frameworks to regulate them — a synergistic interaction among various regulatory variables as elaborated in Chapter 4 — should at least be reasonably expected to be both effective and efficient. This implies that the desired outcomes should be attainable with a justified level of resource expenditure, ensuring that the regulatory objectives are achieved with optimal effort.

Question 2:

Which conflicts of interests does regulation need to accommodate?

To address the trade-offs the regulation of psychoactive products faces, regulations must – in the view of the FCAND – adeptly balance six paramount guiding principles:

- The right to make free and informed decisions regarding consumption.
- Protection of health and youth welfare.
- The safety of everyone, especially those third parties who are not directly involved in but still affected by markets for psychoactive substances.
- The proportionality and comparability of State interventions.
- Economic freedom and the promotion of economic prosperity.
- Adherence to scientific evidence and findings.

This balanced approach aims to ensure that regulatory measures are not only effective and equitable but also rooted in empirical evidence, thereby safeguarding individual freedoms while promoting public health and safety.

Question 3:

To what extent do current policies already meet these requirements?

On the basis of an in-depth analysis of the regulation of 16 psychoactive products, the FCAND identifies three patterns in current regulatory policies:

- Tobacco products, e-cigarettes and alcohol are legally available products and regulation is very light. The regulation does not adequately take account of the health-, dependency- and other risks associated with their use. They can be described as **underregulated**.
- Cannabis, cocaine, ecstasy, heroin and hallucinogens are banned substances under the Narcotics Act (NarcA), which means that (with some exceptions) manufacture and trade or distribution, possession and use of these products are illegal. In the FCAND's view, blanket bans as the tightest form of regulation exaggerate the actual risks and entail too many unintended side effects (in particular the loss of tax revenues and the emergence of criminal networks). These substances can be described as **overregulated**.
- Medicines such as benzodiazepines and prescription opioids, casino games, betting and gambling have in common that the discrepancy between current and desirable regulation is **less wide**.

Based on the analysis outlined in this report, the FCAND has formulated three broad recommendations for policymaking concerned with psychoactive products:

Recommendation 1

The regulation of psychoactive products should be evidence-based, risk-sensitive and coherent across various products. Critically reviewing current policies is of utmost importance to achieve this goal.

Recommendation 2

The regulation of psychoactive products should balance conflicting interests in a transparent way. It should be based on an overarching framework that can be applied to all psychoactive products.

Recommendation 3

The regulation of psychoactive products should transcend the dichotomy of legal and illegal products. Rather, it should consider risk as the main variable to be regulated.

In order to follow-up on these recommendations, the FCAND suggests:

- Continuing the approach currently taken with cannabis when considering the regulation of other, currently prohibited, psychoactive products. Specifically, this means conducting pilot projects to gather scientifically sound and reliable evidence on how markets for psychoactive products can be regulated in a way that enables their use for those who choose to use them and – at the same time – creates a regulatory environment which mitigates the risks stemming from this consumption. Such pilot projects create the evidence base for political decisions on how different psychoactive products can be regulated. This approach should be extended beyond cannabis to include other psychoactive products that are currently illegal.
- Developing and implementing a risk-sensitive way of reinforcing the regulatory mix for currently legal psychoactive products. Good examples from the field of gambling (e.g. sales licences, social protection measures) can and should be evaluated critically and adopted for other products whose current regulation is seen as too lenient by the FCAND.

The overarching goal of the FCAND's proposals is to provide guidance on how to find compromises that take account of the conflicting interests and demands – and at the same time respect, and, where necessary, enhance civil liberties and the State's responsibility to care for its citizens. Bans should be replaced by regulatory mixes that balance personal responsibility, commercial freedom and protection of those in particularly vulnerable situations.

Bern, June 2024

The Federal Commission for Issues relating to Addiction and the Prevention of Non-Communicable Diseases (FCAND) is an extra-parliamentary expert commission. It is appointed by the Federal Council – the government of Switzerland. It advises the Federal Council on matters that concern the field of addiction. The FCAND succeeded the Federal Commission for Alcohol-related Issues (FCAL), the Federal Commission for Tobacco Control (FCTOC) and the Federal Commission for Addiction Issues (FCAI) and exists in its current form since January 2020.

The FCAND is a group of 20 experts from the fields of health promotion and prevention, social sciences, medicine, addiction services and therapy, justice and law enforcement, health equity and health communications. It is chaired by Matthias Weishaupt, former cantonal councillor for Appenzell Ausserrhoden and head of the Department for Health and Social Affairs of the canton of Appenzell Ausserrhoden (2006–19).

The FCAND is an independent body. Its political, technical and professional opinions do not reflect official positions of the Federal Council or the Federal Administration. However, the FCAND is administratively affiliated with the Federal Department of Home Affairs FDHA and its secretariat is part of the Federal Office of Public Health's Division of Prevention of Non-communicable diseases.

This report was compiled under the leadership of Christian Schneider (vice-chair of the FCAND, strategic analyst at the Zurich cantonal police) and Frank Zobel (member of the FCAND, deputy director and co-head of the research department at Addiction Switzerland).

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1. Introduction

How should the State regulate the risks stemming from psychoactive products?

As an extra-parliamentary expert commission mandated to advise the Swiss government on issues of addiction, the Federal Commission for Issues relating to Addiction and the Prevention of Non-Communicable Diseases (FCAND) has been concerned with this question since its appointment in 2020. With this report, the FCAND aspires to move beyond problem diagnosis and provide policymakers with a framework to design regulatory policies for psychoactive products in an evidence-based, risk-sensitive and coherent way.

In a white paper on the regulatory landscape of psychoactive products in Switzerland published in 2022 (*Die Regulierung psychoaktiver Produkte in der Schweiz* (Schneider & Zobel et al. 2022)), the FCAND provided an overview of the regulatory policy options currently in place in Switzerland. The report concluded that "(…), isolated examples of good practice can be identified in the regulation of tobacco, alcohol and gambling. However, seen from an overarching perspective (…) the regulatory instruments currently used in Switzerland are not appropriate to effectively and coherently minimise the harm to health caused by various psychoactive products." (3) The policy landscape on psychoactive product regulation was considered an "uncoordinated patchwork" (20). The ambition of this report is to envision a framework that helps to overcome this situation.

The report starts by setting out criteria to decide whether **regulation is needed** for a given psychoactive product (▶ Chapter 3).

It then goes on to highlight **26 regulatory tools already available to policymakers to regulate markets for psychoactive products** (▶ Chapter 4). Figuratively speaking, the chapter discusses which levers political decisionmakers have at their disposal to minimise the harms and risks associated with psychoactive products. These levers – called "regulatory tools" in this report – are the building blocks on which an overarching framework for regulating psychoactive products can be created.

The report goes on to identify **guiding principles for the regulation of psychoactive products** (▶ Chapter 5). These principles provide guidance on how the 26 regulatory tools in the policy toolkit for psychoactive product regulation should be used. The FCAND identifies six overarching regulatory principles that must be balanced to design coherent policies for psychoactive product regulation: freedom of informed consumption choices; health and youth protection; safety; proportionality and comparability; prosperity; and an evidence-based approach.

In a subsequent step, these regulatory principles are applied to 16 psychoactive products, some of which are already regulated today and others are not, either because they are prohibited or because there is virtually no restriction on their production, distribution and use. For some of these products, by way of example, the report gauges the gap between current regulations and an evidence-based, risk-sensitive, and coherent **regulatory mix** as proposed by the FCAND (▶ Chapter 6).

From this analysis the report then derives a **regulation typology** (▶ Chapter 7). Three regulatory patterns are identified: underregulated products (▶ Chapter 7.1), overregulated products (▶ Chapter 7.2) and products with moderate or negligible need for optimisation (▶ Chapter 7.3).

Chapter 8 draws **conclusions and makes recommendations** for policymakers. These aim at providing guidance for current and future policymaking processes.[1]

This report is an invitation to policymakers to reflect on the way psychoactive products are regulated in Switzerland. It can serve as guidance for discussions and a framework for policymaking processes. It does not, however, provide solutions to current dilemmas in policymaking.

1 A detailed analysis of which legislation would need to be amended in what way to make regulatory policies more evidence-based, risk-sensitive and coherent lies beyond the scope of the present report.

2. Preliminary considerations

2.1 Definitions

This chapter defines the key terms of this report.

- Psychoactive products
- Regulation
- Risk
- Harmfulness

Psychoactive products
are substances, services and other forms of products that have a mind-altering effect or that can cause psychological and/or physical dependency. On the one hand, they include all psychoactive substances such as cannabis, cocaine, heroin, nicotine/tobacco products and alcoholic drinks. They also include services that can cause addiction. Most importantly, this category includes gambling and gaming (Schneider et al. 2022,5). This report examines the regulation of 16 different psychoactive products.

Regulation
– defined broadly – describes all measures available to government actors that seek to influence the visibility, availability, accessibility and attractiveness of products and behaviours (see also Schneider et al. 2022, 5). Regulation in the realm of psychoactive products can either promote consumption patterns and behaviours desired by the government (for example by granting certain goods, products or sales channels preferential tax treatment or subsidies), or counter undesirable ones (for example by levying special consumption taxes on certain goods. ► Art. 131 Cst.). Chapter 4 discusses 26 commonly-used measures to regulate psychoactive products (henceforth called "regulatory tools" for the sake of brevity). As these 26 measures in the "toolkit" for regulating psychoactive substances are in use today in some form or other in Switzerland, they are rooted in constitutional principles. Or as the FCAND has stated in its previous report on the current landscape of the regulation of psychoactive substances: "These rules and tools are set out in Acts, ordinances and other legislative documents" (Schneider et al. 2022, 6).

Risk
describes the likelihood of harm occurring. In the context of this report, harm refers to negative health, social, and/or economic consequences stemming from the ways in which psychoactive products are used at the level of the individual user, and are dealt with by our society and in politics. Measures to regulate these risks are intended to reduce the likelihood of health, social, and/or economic harm occurring.[2]

Harmfulness
describes the interplay between likelihood of harm occurring (risk) and extent of harm (consequences). (Or in mathematical terms: harmfulness = likelihood of harm occurring x extent of the harm).

2.2 Methodology

This report is part of the broader engagement of the FCAND with the rules that regulate psychoactive products in Switzerland. It follows up on insights gained from a previous report analysing the current state of regulation in Switzerland from a comparative perspective (*Die Regulierung psychoaktiver Produkte in der Schweiz* (Schneider et al. 2022)), which identified the need for more coherent regulation of psychoactive products in Switzerland.

The report is based on the outcomes of three full-day workshops conducted between December 2022 and April 2023 in which the members of the FCAND serving as the authors of this report – together with an external facilitator[3] – developed the core elements of the framework presented here. A draft of the report was finished in early summer 2023; all references to laws and regulations in this report refer to this date (some of which had changed by the time this report was published in English). The draft report was discussed and refined at two plenary sessions of the FCAND in June and November 2023, respectively. The final report was adopted by the FCAND in February 2024.

In drafting this report the FCAND drew on the current state of scientific evidence as well as the experience and practical knowledge of its members. The FCAND is aware that there are other ways of approaching the question of how to regulate psychoactive products besides the public health perspective it applies here. It should also be noted that – in the context of this report – it was not possible for the FCAND to systematically map all empirical evidence for how the 26 regulatory variables discussed in chapter 4 (▶ Chapter 4) act in various contexts and under different circumstances.

2 The FCAND uses the following definition of harm reduction: "Harm reduction refers to measures that seek to reduce the psychological and physical consequences of using psychoactive products for users and those close to them (family members). It therefore helps improve the health of people who use psychoactive products and their immediate social environment. Cessation or reduction of use is not a condition for taking part in harm reduction measures. Instead, offerings should be oriented so as to enable responsible use of psychoactive products and to help minimise the harm to health/complications associated with consumption in direct and indirect ways."

3 Markus Theunert (Social Affairs GmbH)

3. Determining the need for regulation of psychoactive products

In 2003 Babor et al. published their highly-regarded and pioneering book *Alcohol: No Ordinary Commodity.* The book's core argument is that alcohol should not be seen as an ordinary product: it has toxic effects, is addictive, and can cause states of intoxication associated with psychomotor, cognitive and emotional changes. The book argues that the potential danger of alcohol not only justifies but even calls for regulation that is commensurate with the specific potential risk.

Other psychoactive products could also be described as not ordinary in this sense. They all entail potential risk to those who use them and, in some cases, to society more broadly. This raises the question if, and to what extent, the State is obliged to regulate psychoactive products in order to protect its citizens.

For example, in 2003 the World Health Organization (WHO) called on member states for the first time to take appropriate measures to prevent people from taking up smoking, to reduce the number of smokers, to tackle nicotine dependency, and to improve protection against passive smoking. In Switzerland, the legislator introduced regulations in the areas of gambling in 1998 when the Gaming Act entered into force. Under this law, a fixed number of 22 casinos were granted a concession to offer a limited set of so called "casino games" (e.g. roulette). These concessions include various requirements for operators intended to prevent gambling addiction (among others that are unrelated to addiction).

The three examples of alcohol, tobacco and gambling illustrate the common challenge psychoactive products present the State with: in order to fulfil its responsibility to protect society from harm, the State is not only justified, but required, to take measures that minimise the harms associated with particularly risky products by influencing how such products are produced, distributed, marketed, taxed, priced and/or consumed.

However, the question that often remains unanswered is which mix of regulatory measures is best suited to control the specific risks of different psychoactive products. Currently, the State attempts to fulfil its responsibility to protect society form the risks that arise from psychoactive substances such as cannabis, heroin and cocaine by banning them entirely. For others, such as tobacco and alcohol, the State attempts to protect society through more targeted interventions, such as advertising restrictions and consumption taxes, while it allows production, sales and some forms of advertisement. This report argues that, from a risk perspective, such State behaviour lacks coherence (▶ Schneider et al. 2022).

Approaching the regulation of psychoactive substances from the perspective of risk and risk minimisation only obscures another element of the role of psychoactive products in our society: Even if it is difficult to prove scientifically, everyday experience shows that the consumption of psychoactive products also has benefits. For example, the use of psychoactive products has calming effects and can improve subjective well-being. Psychoactive products facilitate social interaction, their effects are enjoyable, they allow people to switch off, they open up space for self-discovery, they can be used therapeutically, they facilitate self-management, support affect regulation and are used for self-medication. Discussing the regulation of psychoactive products should therefore not exclusively focus on the risks they pose to individuals and society alike but also on their potential benefits and the individual freedom to choose to consume them. Regulating psychoactive products is more about striking a balance in response to the unresolvable conflicting objectives of freedom and protection than about demonising such products and their effects on society.

In a liberal society, freedom is a core value. This applies both to individual freedom of choice and to trade and commercial freedom and, by extension, to other fundamental rights that may be affected by regulations. If the State restricts such freedoms or fundamental rights, there must be a clearly justifiable need for doing so. In the Swiss context, Article 36 of the Federal Constitution sets out the requirements that must be met in order to restrict civil liberties in accordance with the constitution.[4]

The FCAND recognises that state interventions in markets for psychoactive substances must at least meet the following three criteria[5] in order to be in accordance with constitutional requirements:

Criterion 1
The product must have a psychoactive effect and/or pose a dependency risk.

Criterion 2
Use of the regulated product must entail risk. State interventions are justifiable if there is at least a certain probability that consumption of a psychoactive product will cause harm (= Harmfulness ▶ 2.1). The probability and extent of the harm should be scientifically determined. Cultural and moral judgements should be critically examined and avoided where possible. It is for policymakers to decide what probability and extent of harm appears acceptable.[6]

Risks – in other words, potential harm – can be observed on three levels:

- **Users**: This centres on (potential) physical, psychological, social and economic harm caused by the products themselves and/or specific ways of consuming them and/or the characteristics of consumption patterns. Harm may be caused, for example, by the short- and long-term toxic properties of a product, the associated risk of overdose (mortality risk) and the potential to cause addiction (urge to repeat, withdrawal symptoms etc.).
- **Family members, friends and others directly affected**: This level centres on risks caused by the direct or indirect effect of psychoactive products. A direct risk in the immediate family setting may be an increased propensity for violence due to alcohol consumption and the associated increased risk of family members being victims of domestic violence. A direct risk in the wider social setting may be the danger of getting involved in an accident with a drunk driver or the risk of developing a respiratory disease due to exposure to secondhand smoke. An indirect risk may be, for example, if people neglect school, work, or family responsibilities due to a family member's addiction or get into debt due to such responsibilities.

4 Art. 36 Restrictions on fundamental rights:
1 Restrictions on fundamental rights must have a legal basis. Significant restrictions must have their basis in a federal act. The foregoing does not apply in cases of serious and immediate danger where no other course of action is possible.
2 Restrictions on fundamental rights must be justified in the public interest or for the protection of the fundamental rights of others.
3 Any restrictions on fundamental rights must be proportionate.
4 The essence of fundamental rights is sacrosanct.

5 These three criteria were developed and reviewed by the working group drawing on its expertise at several workshops (▶ Chapter 2.2).

6 Although from a health policy perspective, a precautionary principle/prudence principle/principle of care should apply: manufacturers and sellers of psychoactive substances should – as is the case for the authorisation of therapeutic products, for example – demonstrate the harmlessness of their products, not the affected individuals (organisations) their harmfulness.

- **Economy**: This level is concerned with public expenditure and social costs due to the consumption and trade of psychoactive products. Direct costs may be expenditure to treat and rehabilitate people with an addiction. Indirect costs, as an example, may stem from losses in productivity that must be borne by the public.

Care must be taken to clarify (▶ Figure 1) how these risks relate to each other and how they are weighted. A distinction should also be drawn between short- and long-term consequences of harm. Figure 1 shows that the criterion 'risk' requires closer examination and raises complex questions, including those surrounding ethical considerations.

	Individual	Others	Society
Immediate risk[7]	• risk of overdose • direct somatic risks of acute intoxication • associated risks of acute intoxication	• direct physical risks (e.g. increased propensity for violence under the influence of alcohol) • indirect risks to others (e.g. overburdened hospital accident and emergency departments)	• costs directly arising from intoxication with psychoactive substances (e.g. from emergency/hospital treatment for alcohol poisoning or a drug-induced accident)
Long-term risk[8]	• somatic risks • psychological risks • social risks (e.g. withdrawal from a circle of friends due to dependency, debts)	• changes to relationship(s) caused by consumption and dependency • neglect of an individual's responsibilities to those close to them • risk of co-dependency	• direct costs (e.g. costs of treatment, therapy and reintegration) • indirect costs (e.g. loss of productive years of life, social welfare costs) • non-material (e.g. high psychological stress levels in children from families affected by addiction)

Figure 1: Risk dimensions

7 I.e. risks with a direct causal link to intoxication

8 I.e. risks associated with repeated use of a psychoactive product

Criterion 3
Regulations must be effective and efficient. That means:

a. Regulations must be suited to achieving the desired impact.
   It must be demonstrated or at least be plausible whether/that measures taken to regulate markets for psychoactive products have the desired effect.

b. The expected benefits of regulation must justify regulatory costs (e.g. feasibility, implementation costs, restrictions for third parties, monetary costs). Benefits and costs may be both material (e.g. financial costs) and non-material (e.g. restrictions on freedom).

This implies that it might not be desirable to regulate all goods where consumption may cause problems, as potential improvements stemming from regulatory measures must be balanced against their costs.

The two examples below illustrate the logic of hierarchy of criteria developed here to determine if a given psychoactive product should be regulated or not:

- **Caffeine** has psychoactive effects and can be addictive. Criterion 1 is fulfilled. However, the harms of coffee/caffeine consumption are low. Criterion 2 is not fulfilled. Considering the low level of harm, the cost of regulation would be disproportionately high when compared to the potential improvements in public health that could be achieved with regulation. Criterion 3 is therefore not fulfilled either. There is no need for regulation. Caffeine is an ordinary commodity.

- **Cannabis** has psychoactive effects and can be addictive. Criterion 1 is fulfilled. Consumption of cannabis – at least when smoked – is harmful to the airways and poses an array of other health risks. The psychoactive effect of cannabis also affects people's ability to drive a vehicle or operate machinery. This means there is a risk of putting others in danger. Criterion 2 is also fulfilled. Regulation would crack down on a lucrative and uncontrollable black market, so there is at least one plausible benefit to regulation. Criterion 3 is also fulfilled.
  Measures to regulate cannabis should be considered.

4. Regulatory tools for psychoactive product regulation

Regulation can aim to influence the behaviour of actors – firms and individuals – in markets for psychoactive products. These actors operate at various market levels, identified in this report as the levels of production, distribution, marketing, taxation, pricing and consumption/use, including preparatory acts (purchase, cultivation, possession etc.).9 The strictness of regulations or, to put it differently, the density of regulatory measures for each product, can range on a continuum from very low (unrestricted market) to very high (prohibition of production, distribution and use).

Chapters 4.1 to 4.6 discuss 26 regulatory tools. These regulatory tools can be understood as 26 'levers' that policymakers have at their disposal to regulate markets. The configuration of these levers can be adjusted by policymakers according to the risk assessment of each psychoactive product that should be regulated. Taken together, the configuration of these 26 regulatory tools adds up to a product-specific, risk-sensitive "regulatory mix".

It is important to note that the FCAND does not propose any new regulatory tools. All the 26 tools discussed in this chapter are already in use in the regulation of one or more psychoactive products in Switzerland. What is new about the FCAND's proposal is that we argue that all of these tools should at least be considered applicable to all psychoactive products. Furthermore, the regulatory mixes emerging from policymaking processes should be justifiable by the risk profile of any given product. The regulatory mixes applied to different psychoactive products should be coherent and proportional when compared across products: products with higher risks should be subject to stricter/denser regulation than products with a lower risk-profile; products with comparable risks should be subject to a comparably strict/dense, but not necessarily the same, regulatory mix.

In the following, for each variable, examples from the field of addiction show that the relevant instruments are already applied without giving rise to any fundamental problems in terms of legal issues or social perceptions.

9 Regulating preparatory acts (e.g. possession) independently of the issue of consumption does not make much sense from a public health perspective. Regulation of preparatory acts, although not uncommon, is therefore not further discussed in this report.

4.1 Production

The term 'production' comprises producers, importers and wholesalers in equal measure (▶ Schneider & Zobel et al. 2022, 6). It addresses all actors involved in the development of new products, in the manufacture of products in large quantities, and in the supply of these products to the retail trade.

Regulatory 'levers' at the production level are:

Tool 1	Need for a (production) licence or concession and/or the establishment of a compulsory registration for manufacturers (as is customary in the pharmaceuticals sector)

Example: Spirit distilleries require a licence under the Alcohol Ordinance, paragraph 1.[10]

Tool 2	Quantitative restrictions on production (e.g. by setting a limit on the production volume of certain substances)

Examples: The Narcotics Control Ordinance (NarcCO)[11] sets out the requirements that companies must meet to obtain a licence to grow medicinal cannabis. The quantity to be produced is contractually agreed between the producing company and the legally authorised buyer. The producing company can only grow as much cannabis as it is contracted to sell. Unlike in Germany, however, Swissmedic is not a cannabis agency that centrally stipulates the annual production requirements and controls production accordingly.

Tool 3	Qualitative product restrictions (e.g. limitation of certain ingredients or products)

Examples: The Ordinance on Alcoholic Beverages sets out detailed qualitative requirements for the various alcoholic products.[12] – The Tobacco Ordinance also defines qualitative requirements and limits for tobacco products in section 3.[13]

10 www.fedlex.admin.ch/eli/cc/2017/568/de

11 www.fedlex.admin.ch/eli/cc/2011/362/de

12 e.g. in Art. 41: "1 Beer is an alcoholic and carbonated beverage that is made from wort fermented with yeast, to which cone hops or hop products are added. 2 The wort is produced from raw materials containing starch or sugar, and drinking water. 3 Hop products are hop powder, enriched hop powder, hop extract, hop extract powder and isomerised hop extract."

13 fedlex.data.admin.ch/filestore/fedlex.data.admin.ch/eli/cc/2004/688/20190915/de/pdf-a/fedlex-data-admin-ch-eli-cc-2004-688-20190915-de-pdf-a.pdf

4.2 Distribution (retail)

In order for (psychoactive) products to make their way from the producing company or wholesaler to customers or consumers, its distribution must be organised. This pivotal function is performed by retail. "Retailers decide to whom, where and under what conditions psychoactive products are passed on to buyers" (Schneider et al. 2022, 13). Traditionally, retail happens in stores. However, distribution via online channels – particularly in the area of psychoactive products – is becoming ever more important.

Regulatory 'levers' at the distribution level are:

Tool 4 | Type of sales outlets (e.g. pharmacies or similar only)

Examples: Under the Narcotics Lists Ordinance, medicinal cannabis is assigned to Category A, like e.g. cocaine, methamphetamine, morphine and fentanyl.[14] Category A narcotics may be prescribed for medical purposes by doctors who are able to write prescriptions; they may only be dispensed by pharmacies or doctors who are allowed to dispense medication (Art. 3e para. 1 and Art. 13 Narcotics Act).[15] – Under Art. 41 of the Alcohol Act, the sale of spirits by street vendors or itinerant merchants is prohibited.[16]

Tool 5 | (Sales) permit needed

Examples: Every company that wishes to operate casino games in Switzerland must have a site permit and operating licence.[17] – "If you wish to sell spirits in a shop or serve spirits in a restaurant or distribute them online or sell them in fast food stores, you will need a retail permit. This permit must be applied for from the competent canton, i.e. the canton in which trade will be conducted."[18] – Some cantons (e.g. Vaud and Geneva) make the sale of tobacco products dependent on a licence.[19]

Tool 6 | Age restrictions for sale

Examples: In all Swiss cantons, there are regulations according to which spirits can only be dispensed to those aged over 18 and beer/wine to those aged over 16. One exception is the canton of Ticino, which has an age limit of 18 for all alcoholic beverages.[20] – Similarly, there is a minimum age for the sale of tobacco products in most cantons (either 16 or 18).[21] The planned entry into force of the new Tobacco Products Act on 1 July 2024 means there will be a standard age restriction of 18 throughout Switzerland for all tobacco products and e-cigarettes.[22] [23] – The Gambling Act sets out a ban on playing casino games and large-scale games conducted online for those under 18 (Art. 52 para. 1 let. e and Art. 72 para. 1).[24]

14 www.fedlex.admin.ch/eli/cc/2011/363/de

15 www.fedlex.admin.ch/eli/cc/1952/241_241_245/en

16 www.fedlex.admin.ch/eli/cc/48/425_437_457/de#a41

17 www.esbk.admin.ch/esbk/de/home/spielbankenaufsicht/spielbanken.html

18 www.bazg.admin.ch/bazg/en/home/topics/alcohol/spirituosen_verkauf.html; unofficial translation by the authors.

19 www.bag.admin.ch/bag/de/home/strategie-und-politik/politische-auftraege-und-aktionsplaene/politische-auftraege-zur-tabakpraevention/tabakpolitik-kantone.html

20 www.bag.admin.ch/bag/de/home/strategie-und-politik/politische-auftraege-und-aktionsplaene/politische-auftraege-zur-alkoholpraevention/alkoholpraevention-kantone/jugendschutz.html

21 www.bag.admin.ch/bag/de/home/strategie-und-politik/politische-auftraege-und-aktionsplaene/politische-auftraege-zur-tabakpraevention/tabakpolitik-kantone/abgabeverbot-tabakprodukte-kantone.html

22 In this report, e-cigarettes are understood as tobacco-free, nicotine-containing products

23 tinyurl.com/bpazc742

24 www.fedlex.admin.ch/eli/cc/2018/795/de

Tool 7 | Restrictions on the number and concentration of sales outlets

Examples: The Federal Council stipulates the number of casino licences and grants them for a twenty-year period.[25] – 22 cantons have regulations limiting the availability of alcohol (e.g. sale in vending machines, at kiosks or in swimming pools etc.).[26]

Tool 8 | Regulation of online sales channels (e.g. blocking foreign suppliers)

Examples: "In principle, mail-order trade in medicinal products is prohibited." (Art. 27 para. 1 Therapeutic Products Act).[27] The cantons may authorise exceptions in very limited contexts. – Access to the Swiss market is blocked for foreign providers of online lotteries and sports betting. "Under intercantonal law, lotteries and sports betting can only legally be offered in Switzerland through Swisslos and the Loterie Romande. This system also applies to the online sphere [online casino games, author's note]. However, foreign providers can partner with Swiss providers to offer gambling services in Switzerland."[28]

Tool 9 | Restriction of sale times

Example: The cantons of BS, FR, NE, VD and GE have set out restrictions on when alcohol can be sold in their cantonal legislation.[29]

Tool 10 | Restrictions on products offered

Examples: It is prohibited to sell alcoholic beverages to those who are inebriated (regardless of their age).[30] – The cantonal security authorities can also impose restrictions on organisers of top-level sporting events through the permit requirement. They may concern structural or technical measures in stadiums, the use of private security forces, the stadium regulations, the sale of alcohol, access controls and the arrival and return of guest fans."[31] For high-risk games, a total ban on the sale of alcohol should apply "outside of a small number of demarcated and controlled 'VIP areas'".[32]

Tool 11 | Requirements regarding training of staff in sales outlets

Example: Various cantons link the liquor licence to the acquisition of an authorisation or cantonal permit.[33]

Tool 12 | Obligation to inform (in writing)

Example: Art. 88 of the Gambling Ordinance requires the following under 'Information on excessive gambling' (Art. 88 Federal Gambling Ordinance): "Organisers of online games must provide players with clearly visible and easily accessible information on excessive gambling, in particular: a. a method for self-assessing their own gambling behaviour; b. one or more ways of controlling or limiting their gambling; c. the possibility and specific instructions on how to ban themselves from certain games; d. the details of the organiser's social welfare officer; e. the addresses of gambling addiction counselling services recognised by the cantons."[34]

25 www.esbk.admin.ch/esbk/de/home/spielbankenaufsicht/spielbanken.html

26 www.bag.admin.ch/bag/de/home/strategie-und-politik/politische-auftraege-und-aktionsplaene/politische-auftraege-zur-alkoholpraevention/alkoholpraevention-kantone/oertliche-einschraenkungen.html

27 www.fedlex.admin.ch/eli/cc/2001/422/en

28 www.bj.admin.ch/bj/de/home/wirtschaft/geldspiele/faq.html; unofficial translation by the authors

29 www.bag.admin.ch/bag/de/home/strategie-und-politik/politische-auftraege-und-aktionsplaene/politische-auftraege-zur-alkoholpraevention/alkoholpraevention-kantone.html

30 tinyurl.com/42br4dr8

31 kkjpd.ch/themen.html (hooliganism)

32 irf.fhnw.ch/bitstream/handle/11654/11006/Alkoholregelung_Schmid.pdf?sequence=2

33 www.wirtepatent.ch/de/wissen/bewilligungen-gastronomie-145.html

34 www.fedlex.admin.ch/eli/cc/2018/796/de

Tool 13 | Obligation to inform (verbally)

Example: For medical treatments "in principle all healthcare professionals (the responsible healthcare professional, editor's note) in the field of human medicine, dentistry, chiropractic, pharmacy and veterinary medicine in accordance with Art. 1 Medical Professions Act (MedPA) have a duty to inform their patients."[35] The medical duty to inform is also enshrined in Art. 10 of the Code of Ethics of the Swiss Medical Association (FMH).[36] The duty to inform is "legally speaking considered a sine qua non condition in order for the patient to legally exercise their right of self-determination."[37]

Tool 14 | Educating people with problematic consumption patterns

Example: Casinos must protect players from excessive gambling; the measures must be oriented to the potential risk associated with the game in question. (Art. 71 and Art. 73 Gambling Act GamblA). They must provide "information on the risks of the game" and tools for self-monitoring in "easily accessible and readily understandable form" (Art. 77 GamblA). Casinos must also draw up a social concept (Art. 76 GamblA) that must include "suitable and relevant criteria to observe players' gambling behaviour" (Art. 81 para. 1 let. a of the Gambling Ordinance GamblO).[38]

4.3 Marketing level

Marketing is the umbrella term for everything a company does to make sure consumers want its products. Marketing theory traditionally distinguishes four dimensions of marketing, known as the four Ps: product, price, promotion (communication and advertising) and place (sales outlets). In this context, the term marketing will be used in a narrower sense and will be limited to product declaration, product packaging and advertising of the product.

Regulatory 'levers' at the marketing level are:

Tool 15 | Declaration of ingredients

Example: The FDHA Ordinance on Beverages sets out what information the labels of various alcoholic beverages must include (and what requirements the beverage must meet in order to include additional designations, such as 'dry' or 'medium dry'): beer (Art. 66), wine (Art. 75), fortified wine (Art. 85), cider (Art. 94), pomaceous fruit juice at the fermentation stage (Art 101), fruit wine (Art. 105) and spirits (Art. 156 ff.).[39] – The 'Guidance document on human medicinal products' issued by Swissmedic defines where and how the medicinal products must be labelled.[40]

Tool 16 | Warning labels

Example: The FDHA Ordinance on Combined Warnings on Tobacco Products stipulates that all tobacco products offered for sale in Switzerland since 1 January 2010 must bear pictorial warnings on the back of the pack. These rules also apply to tobacco substitutes, e.g. containing CBD hemp (under 1% THC). Text and images are stipulated in detail in the corresponding ordinance.[41]

35 www.klgp.ch/de/022016-vademecum-der-aerztlichen-aufklaerungspflicht-gegenueber-patienten.html (in German)

36 Art. 10 Duty to inform Physicians shall inform their patients in a clear and comprehensible manner about their medical findings, the intended diagnostic and therapeutic measures, their chances of success and the risks, and about any alternative treatments. ▶www.fmh.ch/files/pdf7/standesordnung-fmh.pdf

37 www.fmh.ch/files/pdf7/rechtliche-grundlagen-2020-de.pdf, Seite 37

38 www.klgp.ch/de/022016-vademecum-der-aerztlichen-aufklaerungspflicht-gegenueber-patienten.html

39 www.fedlex.admin.ch/eli/cc/2017/220/de

40 tinyurl.com/2bhaj7f9

41 fedlex.data.admin.ch/filestore/fedlex.data.admin.ch/eli/cc/2007/930/20080101/de/pdf-a/fedlex-data-admin-ch-eli-cc-2007-930-20080101-de-pdf-a.pdf

Tool 17 | Packaging

Example: Swissmedic sets out detailed specifications on what information must feature on the packaging of human medicinal products. This includes, for example, composition, dosage strength, dosage form, route of administration, warning regarding children ('keep out of reach of children'), special warnings, expiry date and storage instructions. There are also specifications regarding the design of packaging for medicinal products on the use of pictures, logos and pictograms.[42] – The Tobacco Ordinance sets out detailed requirements under Articles 11 to 16 regarding the design of tobacco product packaging in terms of content and form.[43]

Tool 18 | Advertising restrictions

Examples: Art. 74 para. 1 of the Federal Gambling Act prohibits intrusive and misleading advertising. Under Art. 74 para. 2 advertising may "not be directed at minors or people barred from playing".[44] – Many cantons prohibit alcohol advertising in certain locations (e.g. In public places in general or in sports facilities) or in certain situations (e.g. screenings of films with a 16 certificate).[45] – Most cantons restrict the advertising of tobacco products.[46] – The advertising of prescription-only medicinal products or for medicines that "are frequently abused or can lead to addiction and dependence" is in principle prohibited under the Therapeutic Products Act (Art. 32 para. 2 let. a and d).

42 tinyurl.com/2bhaj7f9

43 www.fedlex.admin.ch/eli/cc/2004/688/de

44 fedlex.data.admin.ch/filestore/fedlex.data.admin.ch/eli/cc/2018/795/20210101/de/pdf-a/fedlex-data-admin-ch-eli-cc-2018-795-20210101-de-pdf-a.pdf, unofficial translation by the authors.

45 www.bag.admin.ch/bag/de/home/strategie-und-politik/politische-auftraege-und-aktionsplaene/politische-auftraege-zur-alkoholpraevention/alkoholpraevention-kantone/werbeeinschraenkungen.html

46 www.bag.admin.ch/bag/de/home/strategie-und-politik/politische-auftraege-und-aktionsplaene/politische-auftraege-zur-tabakpraevention/tabakpolitik-kantone/werbeeinschraenkungen-kantone.html; unofficial translation by the authors.

4.4 Taxation

By levying taxes, the State can generate revenues and influence markets. Both effects are utilised in the area of psychoactive products.[47] The political sovereignty for controlling or reducing demand for psychoactive products through special taxes on consumption lies with the federal government.

Tool 19 | Level of taxation

Examples: Under Art. 131 Cst. the federal government may levy special consumption taxes on tobacco and tobacco products, spirits, beer, and other goods. The retail price of a packet of cigarettes is currently CHF 9.00 This is made up of the following:[48]

	In CHF	in %
Tax on tobacco	4.61	51.2
Value added tax VAT	0.64	7,1*
SOTA levy (domestic tobacco financing fund tax)	0.026	0,3
Tobacco Prevention Fund levy	0.026	0,3
Industry and trade	3.698	41,1

* i.e. 7.7% of the retail plus excluding VAT
Last updated: December 2022

Not all tobacco products are taxed in the same way. For example, chewing tobacco and snuff are taxed at 6% of the retail price.[49] The Federal Council and Parliament plan to introduce taxes on electronic cigarettes in the near future. This tax will amount to 20 centimes per millilitre for reusable e-cigarettes and CHF 1 per millilitre for disposable e-cigarettes. The corresponding amendment to the Tobacco Taxation Act was approved by Parliament on 16 June 2023; the referendum period expired on 5 October 2023.[50]

47 In 2020, the federal government generated CHF 2.1 billion through the taxation of tobacco products. These revenues flow into the general federal treasury to cover OASI and equate to around 5% of all OASI revenues. At the same time, taxation should expressly control/reduce demand. ▶ tinyurl.com/azz8y7cr

48 www.bag.admin.ch/bag/de/home/strategie-und-politik/politische-auftraege-und-aktionsplaene/politische-auftraege-zur-tabakpraevention/tabakpolitik-schweiz/tabaksteuer.html

49 www.bazg.admin.ch/bazg/en/home/documentation/publications/forms.html

50 www.parlament.ch/de/ratsbetrieb/suche-curia-vista/geschaeft?AffairId=20220069#:~:text=Mit%20der%20nun%20verabschiedeten%20Botschaft,CHF%200.20%20pro%20Milliliter%20Flüssigkeit

Alcohol taxation differs according to beverage categories and there are two different measuring methods. The system is as follows:[51]

Tax rates

Product	Tax in CHF	Responsibility
Spirits	29.– / l r.A.	ALK (Alcohol Act)
Ethanol for consumption	29.– / l r.A.	ALK (Alcohol Act)
Ethanol for industrial purposes	0.–	ALK (Alcohol Act)
Alcopops [a)]	116.– / l r.A.	ALK (Alcohol Act)
Sweet wines and Vermouth	14.50 / l r.A.	ALK (Foodstuffs Act)
Light beer (up to 10.0° Plato)	16.88 / hl	TABI (Foodstuffs Act)
Normal and special beer (10.1 to 14.0° Plato)	25.32 / hl	TABI (Foodstuffs Act)
Strong beer (over 14° Plato)	33.76 / hl	TABI (Foodstuffs Act)
Natural wine up to 18 % vol [b)]	0.–	FSVO (Foodstuffs Act)

[a)] Because of the risk of abuse (start of alcohol consumption at an early stage) by young people, the tax rate is quadrupled for alcopops.

[b)] The Foodstuffs Act gives a definition of natural wine. In case of doubt, the ALK uses laboratory analyses to determine whether an alcoholic beverage is taxed or not.

Casinos have to pay a levy on the gross gambling revenue (= difference between the stakes and the winnings paid out) (Art. 119 GamblA). The rate amounts to minimum 40% and maximum 80% (Art. 120 para. 2 GamblA) for terrestrial services and between 20% and 80% for online services.[52] The rate of the levy is intended to allow an "appropriate return to be achieved on the invested capital" (Art. 120 para. 1 GamblA).

Tool 20 | Use of tax revenues

Example: Under Art. 131 para. 3 Cst., 10% of the net proceeds from the taxation of distilled spirits must be paid out to the cantons (known as the "alcohol tenth"). Use of this is earmarked "to fight the causes and effects of substance addiction".[53] – In accordance with Art. 28 para. 2 let. c of the Tobacco Taxation Act, a levy of 2.6 cents per pack of cigarettes sold is used to finance a Tobacco Prevention Fund. This generates some CHF 13 million a year to prevent and reduce problems associated with tobacco use.[54]

51 www.bazg.admin.ch/bazg/en/home/topics/alcohol/steuersaetze.html

52 www.fedlex.admin.ch/eli/cc/2018/795/de

53 www.fedlex.admin.ch/eli/cc/1999/404/e

54 tinyurl.com/bdeynnd8

4.5 Pricing

In addition to the taxation of psychoactive products, the State can also set minimum and fixed prices to directly influence the price and therefore demand for psychoactive products.

Tool 21 | Minimum price

Examples: In the cantons of AI, BE, NE, TI and VD, flat-rate prices for alcohol (all you can drink offers) are prohibited.[55] – Some cantonal laws (such as the Hospitality Act in the canton of Zurich, Art. 23) [56] stipulate that the cheapest available drink must not be alcoholic. – Under Art. 54 para. 1 of the Gambling Ordinance, the "maximum stake for automated games in terrestrial casinos with a B licence is CHF 25 per game."[57]

Tool 22 | Fixed price

Example: All medicines that feature on the list of pharmaceutical specialities of the Federal Office of Public Health (FOPH) have a set ex-factory price[58] that is reviewed every three years.

4.6 Consumption level

State regulation of demand through restrictions on the consumption of psychoactive products has a long tradition as the inclusion of a substance in the Narcotics Act of 1951 also criminalised individual consumption. In order to impact individual consumption, however, the State must not completely ban the consumption of psychoactive products. It also has specific effective regulatory variables at its disposal.

Tool 23 | Restrictions on consumption in specific places (e.g. not in public places, not near school buildings etc.)

Examples: The Federal Act on Protection Against Passive Smoking imposes a blanket smoking ban in public places.[59] – In some cantons – for example in Bern – the use of e-cigarettes is banned everywhere that smoking is.[60]

Tool 24 | Restrictions on consumption at specific times

Example: Between 2008 and 2020, the town of Chur had a night-time ban on the consumption of alcohol in public places between 12.30am and 7am.

55 www.bag.admin.ch/bag/de/home/strategie-und-politik/politische-auftraege-und-aktionsplaene/politische-auftraege-zur-alkoholpraevention/alkoholpraevention-kantone/jugendschutz.html

56 http://www2.zhlex.zh.ch/appl/zhlex_r.nsf/WebView/240F8A228DDB0728C12581F7002DE149/$File/935.11_1.12.96_99.pdf

57 www.fedlex.admin.ch/eli/cc/2018/796/de

58 Art. 67 para. 1 ter of the Health Insurance Ordinance of 27 June 1995

59 www.fedlex.admin.ch/eli/cc/2009/766/de

60 www.sta.be.ch/de/start.html?newsID=edd3c1d8-51f2-4d88-90e6-33cbc91a3322

Tool 25 | Restrictions on consumption in specific situations (e.g. while driving, in the workplace)

Example: "Anyone who does not have the necessary physical and mental capability due to being under the influence of alcohol, narcotics or medicinal products, or for other reasons, shall be deemed unfit to drive during this time and may not control a vehicle." (Art. 31 para. 2 Road Traffic Act). On the other hand, partaking in 'secondary activities' while driving (such as smoking) is allowed, as long as the duty of care in accordance with Art. 31 para. 1 RTA is complied with.[61]

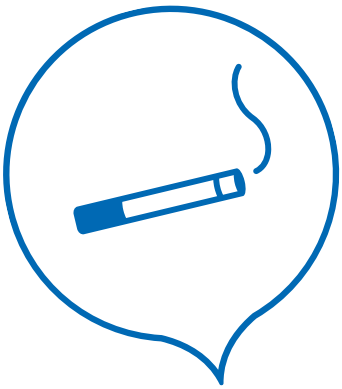
Tool 26 | Protection of others (e.g. from passive smoking)

Example: The Passive Smoking Act regulates "protection from secondhand smoke in enclosed spaces that are accessible to the public or that serve as a workplace for more than one person" (Art. 1 para. 1).[62]

The list of the six regulatory dimensions with their 26 regulatory tools (▶ Chapters 4.1 to 4.6) shows what measures the Swiss government already has at its disposal to regulate psychoactive products.[63] It also illustrates the wealth of experience in the application of individual regulatory tools, as some of them have been in use in different contexts for decades. This report therefore takes a much less experimental approach than it may seem at first glance. It does not propose inventing new regulatory tools; it calls for a coherent and risk-sensitive use of existing ones in the regulation of all psychoactive products that should be regulated due to their risk profile (▶ Chapter 3).

However, this chapter also illustrates why Switzerland's addiction policy can – in the FCAND's view – appropriately be described as a 'patchwork'. There is no concept that ensures that regulatory tools are applied with a certain degree of uniformity and traceability across different psychoactive products.

Although it may seem so at first glance, the FCAND is not inviting policymakers to embark on a big experiment in the regulation of psychoactive substances. It merely suggests that established regulatory tools should be adapted in a risk-sensitive way to create regulatory mixes that correspond to the risk profiles of different substances.



61 www.parlament.ch/de/ratsbetrieb/suche-curia-vista/geschaeft?AffairId=20184255, unofficial translation by the authors

62 www.fedlex.admin.ch/eli/cc/2009/766/de, unofficial translation by the authors

63 The list is not exhaustive. The legislator could also use or create additional instruments.

5. Guiding principles for regulating psychoactive products

The regulation of psychoactive products has to accommodate conflicting yet justifiable interests. In a liberal society, compromises must be found between economic interests, social and health perspectives, individual and collective freedoms, and increasingly, environmental policy challenges (▶ Schneider et al. 2022, 23). Otherwise, political solutions to problems will not be viable.

The FCAND argued in its previous report that, when viewed from a public health perspective, the coherent regulation of psychoactive products has to overcome a double challenge: "On the one hand, moral judgments that create inequality should be avoided, while on the other, measures to protect the health of individuals and the overall population should be promoted and coherently implemented. Both challenges are substantial. It is important to counter 'moral entrepreneurs' who attempt to impose a view that is not commensurate with the actual danger of the substances and behaviours. At the same time, economic players for whom any regulation is an unnecessary obstacle to revenue generation need to be curtailed." (Schneider et al. 2022, 23).

In order to strike the complex balance between such conflicting interests for the regulation of psychoactive products, the FCAND recommends developing coherent regulation along the following six regulatory guiding principles:

1. Enabling the freedom of informed choice

In order to assess the risks they are exposing themselves to by consuming psychoactive products, people need skills and information that enable them to weigh the cost and benefits of the trade-offs they are entering. Information, health literacy and risk competence allow them to consciously take, accept and minimise risks (by abstaining or cutting down, making an informed product choice and/or by carefully determining a suitable consumption setting). The principle of freedom of informed choice builds on a basic trust in the competences and capacities of consumers and a fundamental respect for civil liberties (including the right to harm oneself and the individual's right of self-determination). Promoting freedom of informed choice expands the options available for individuals and should be understood as the opposite of 'nanny state'-approaches to the regulation of psychoactive products.

2. Protecting health and youth

The State has a responsibility to protect its people, including their health. Essentially, this extends to society as a whole, but applies even more so to particularly vulnerable people (e.g. children). Policies to regulate psychoactive products cover central aspects of this responsibility to protect, including preventing addiction, limiting self-endangerment, minimising suffering, preventing unnecessary consumption incentives, countering excesses, and reducing subsequent costs to the economy.

3. Providing safety and security (in public/for the public/product safety/for users)

The State also has a responsibility to ensure the safety and security of its citizens. In terms of psychoactive products, this covers various aspects: consumers should know what they are consuming and the conditions under which psychoactive products are produced, while supply chains should be controlled. Crime should be prevented and efforts made to crack down on the black market. Likewise, dangers and disturbances to others should be limited through State action (e.g. in road traffic, through vandalism, through nocturnal disturbance etc.). Isolated solutions should be avoided as far as possible, as the differences in regulations between jurisdictions – especially in a federal state like Switzerland – will be exploited by producers and customers alike.

4. Promoting prosperity

The State also has a responsibility to guarantee and support the innovative capability and productivity of the Swiss economy – which includes healthcare – in a sustainable way. To do so, it must accommodate business interests and avoid unnecessary burdens on them. The productivity and health of the workforce should be safeguarded and promoted. The loss of capital and tax revenues to illegal markets should be prevented. The State should provide an environment in which businesses are incentivised to create jobs. Regulations should place the smallest possible burden on the police, and relieve pressure on them as much as possible in order to ensure that taxes are used in a meaningful way. Regulations should be designed to be socially acceptable. They should reinforce the principle that those who create a burden on society by their actions are also those who primarily pay for it through earmarked taxation to promote societal cohesion and solidarity.

5. Enhancing proportionality and comparability

Arbitrary, ideological and one-sided regulations should be abolished or prevented. Regulations must be viable, have targeted impact, and should be proportional. The ratio between the cost of regulation and its returns in monetary or non-monetary terms should be positive. Market distortions should be reduced/prevented where possible. Regulation needs to be made more coherent: comparable risks should be regulated in a comparable way. The coherence and transparency of regulatory measures should be promoted and methods of comparing regulatory tools should also be improved.

6. Focusing on scientific evidence

Regulations should be guided by scientific evidence. It should be understood as a dynamic process that aims at gradually optimising and harmonising the way in which the State deals with societal risks emerging from markets for psychoactive products. Implementation must be measured with overarching metrics. The effectiveness of regulatory policies should be evaluated.

In short, risks are appropriately regulated if the regulatory mix prevents and minimises as much potential harm as possible with the fewest possible restrictions and unintended consequences.

6. Contrasting current and risk-sensitive regulation

In order to derive guidelines for coherent and effective regulation of psychoactive products, a careful analysis is required. The FCAND analysed in detail the current regulatory mixes of 16 psychoactive products. It then contrasted the current regulation with preferable regulatory mixes that are in accordance with the regulatory guiding principles discussed in ▶ Chapter 5. In doing so, it attempted to show how conflicting interests can be balanced in a more risk-sensitive way in the regulation of these 16 psychoactive substances.

Of the psychoactive products analysed, eleven are substance-based and five are non-substance-based:

Substance-based

1 Tobacco products
2 e-cigarettes[64]/other tobacco-free products containing nicotine
3 Alcohol
4 Cannabis
5 Cocaine/crack
6 Ecstasy
7 Heroin
8 Hallucinogens
9 Benzodiazepines
10 Prescription opioids
11 Caffeine (as an example)

Non-substance-based

12 Casino games
13 Lottery games
14 Video games
15 Betting
16 Online pornography (as an example)

In this chapter the regulatory profiles of three of these products are presented by way of example. This aims to help better understand how the regulatory mixes of the remaining 13 products were classified. The classification of all 16 products analysed for this report is discussed in ▶ Chap. 7.

For each of the 26 regulatory tools (▶ Chap. 4) the 'strictness of regulation' was assessed on a six-point scale:

1 no regulation
2 minimal regulation
3 light regulation
4 substantial regulation
5 tight regulation
6 ban (deemed the most extreme form of regulation)

64 In this report, e-cigarettes are understood as tobacco-free, nicotine-containing products.

In the following visual representations of this analysis, the current regulatory mix is shown in blue. It is important to note that the current regulatory mixes do not consider the effectiveness of individual regulatory tools. Rather, what has been considered for our analysis is the legal situation. A market for a particular product may exist even though it is prohibited, which means that the intended effect of a regulatory mix has not been achieved. For the analysis, it is nevertheless considered as strictly regulated as possible (i.e. 6 = ban)

Shown in green are the proposals of the FCAND for a risk-sensitive and coherent future regulation (according to the criteria and principles set out in ▶ Chap. 3 and Chap. 5). Bans are shown in red because a ban can be considered as a regulatory class in itself.
It should be noted at this point that not all of the 26 regulatory tools discussed in this report can be applied to all 16 psychoactive products under scrutiny in the same way (or at all). For example, an obligation to inform consumers about risks verbally at the point of sale (regulatory tool 13) requires face-to-face contact with consumers, which in the case of online sale, for example, is not necessarily possible.

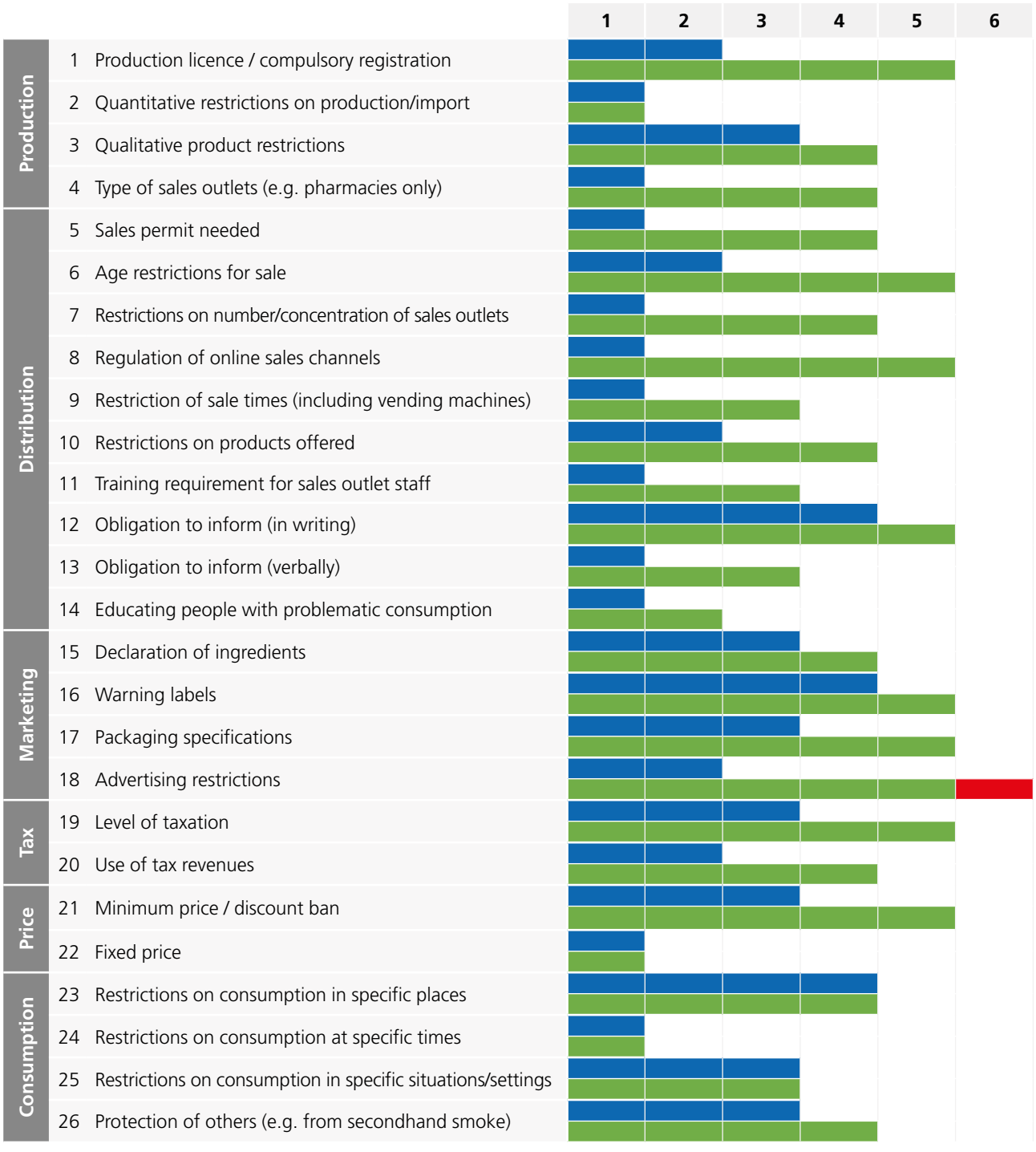
The visualisations of the three examples tobacco, cannabis and lotteries show three regulatory patterns:

- **Tobacco products** The visual representation of the analysis of the tobacco regulatory mix shows more green (risk-sensitive regulation) than blue bars (current regulation). The FCAND considers the current regulatory mix for tobacco in relation to its risks (addictiveness and other potential for harm) as not strict enough[65] (cf. ▶ Chap. 7.1). The current regulatory mix includes no bans on any regulatory tool. The FCAND, on the other hand, deems a ban on advertising desirable from a risk-sensitive perspective.
- **Cannabis** The visual representation of the analysis of the cannabis regulatory mix shows more blue and red bars (current regulation and bans, respectively) than green ones (risk-sensitive regulation). The FCAND considers the current regulatory mix for cannabis in relation to its risks (addictiveness and other potential for harm) as too strict (cf. ▶ Chap. 7.2). From the FCAND's perspective, only advertising should remain prohibited.
- **Lotteries** In the visual representation of the analysis of the lotteries regulatory mix, the blue (current regulation) and green bars (risk-sensitive regulation) mostly match. In the FCAND's view, there is only a small gap between the existing and a desirable regulatory mix. Lotteries are already tightly regulated. At a relatively high level of regulation there is a need for optimisation to take even more adequate account of the risks associated with the provision of lotteries (cf. ▶ Chap. 7.3).

Chapter 7 summarises the results for all 16 psychoactive products analysed and assigns them to three groups: underregulated products, overregulated products, and products showing a smaller gap between current and risk-sensitive regulation.

65 In accordance with the applicable legislation at the time the report was published. The new Tobacco Products Act, which is scheduled to enter into force on 1 July 2024, will see tobacco subject to slightly more stringent regulations.

Tobacco products

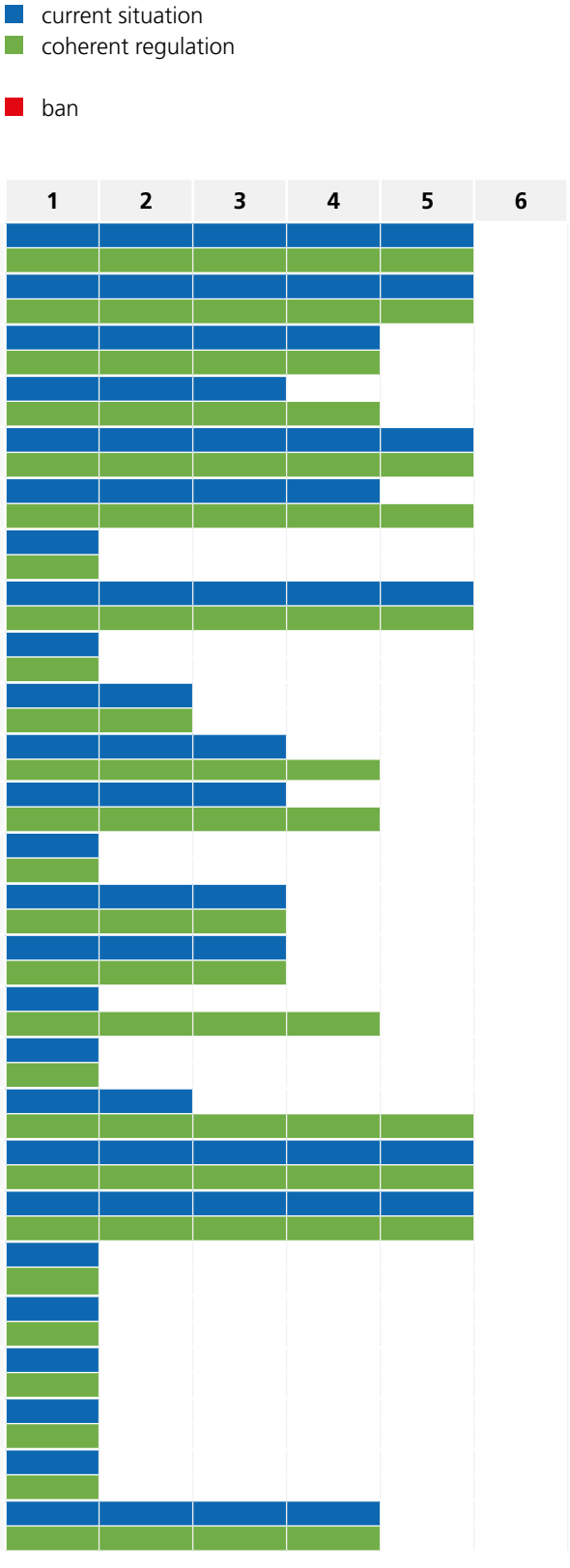


1 = none 2 = minimal 3 = light 4 = substantial 5 = tight 6 = ban

Cannabis

1 = none 2 = minimal 3 = light 4 = substantial 5 = tight 6 = ban

Lotterien



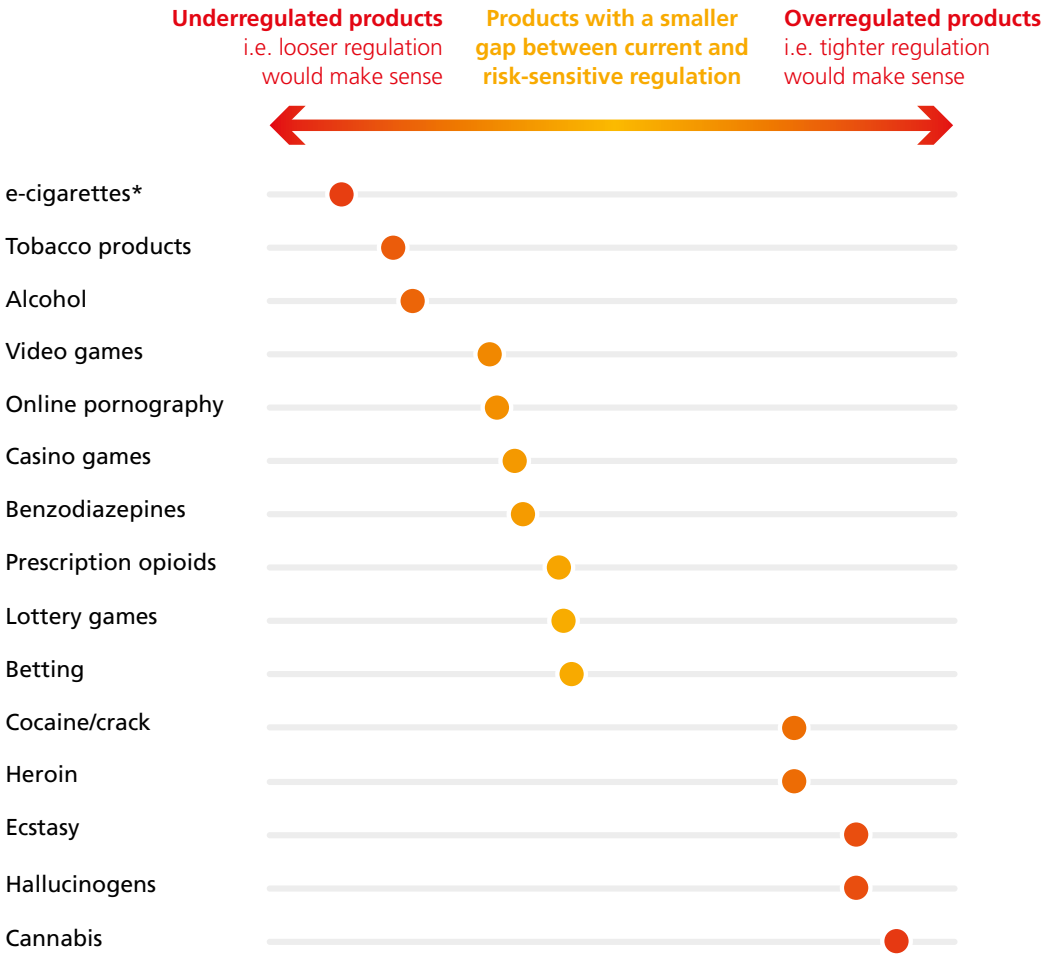
1 = none 2 = minimal 3 = light 4 = substantial 5 = tight 6 = ban

This assessment concerns the provisions of federal law. Regulation might vary significantly among cantons.

7. Regulation typology

Besides the three psychoactive products whose regulatory mixes are detailed in the previous chapter, the FCAND analysed the regulatory mixes of 13 additional products. For the sake of brevity, not all 26 regulatory variables are presented for each product in this report. Instead, a score was calculated to measure how much and in which direction the current regulatory mix deviates from a – in the FCAND's view – desirable, risk-sensitive regulatory mix.

Caffeine was also evaluated by the FCAND to validate the concept of coherent regulation as described in Chapter 6. However, it is no longer listed in the following because, according to the assessment of the FCAND, caffeine does not meet all the criteria for regulation and therefore does not require regulation (see Chapter 3, p.14).



- underregulated products (▶ Chap. 7.1)
- overregulated products (▶ Chap. 7.2)
- products where there is less need for optimisation (▶ Chap. 7.3)

* In this report, e-cigarettes are understood as tobacco-free, nicotine-containing products.

Figure 2 Difference between current regulation and technically desirable regulation

These scores are the sum of all deviations of all 26 regulatory tools. Negative scores mean that the FCAND estimated that a stricter regulatory mix was needed for an adequately risk-sensitive regulation of a product than was currently in place. Hence, these products are underregulated. The opposite applies to products with positive scores: they are overregulated.

7.1 Underregulated products

(1) Tobacco products, (2) e-cigarettes and (3) alcohol are legally available products and are relatively lightly regulated. Yet their consumption entails health and dependency risks and other potential harms (e.g. "social withdrawal"). In accordance with the regulatory guiding principles defined above, the FCAND considers them to be underregulated. The largest deficits in regulation are located at the level of marketing and in particular in terms of advertising restrictions. The FCAND also sees potential in the area of distribution and, to a lesser extent, in production.

7.2 Overregulated products

(4) Cannabis, (5) cocaine, (6) ecstasy, (7) heroin and (8) hallucinogens are prohibited substances under the Narcotics Act (NarcA), for which the manufacture and trade or distribution, possession and use are illegal outside a very limited range of scientific and medical purposes. In practice there are exceptions, particularly for cannabis.[66] Cannabis is therefore the only currently illegal substance for which the FCAND sees a relatively small gap between current regulations and what would be desirable from a risk-sensitive approach when it comes to consumption. For the other illegal substances considered, the FCAND identified a much wider gap because the consumption of these substances is still banned outright.

7.3 Products with a smaller gap between current and risk-sensitive regulation

Compared with the products above, the FCAND identified a smaller gap between the regulatory mix that currently applies and a risk-sensitive regulatory mix for (9) benzodiazepines, (10) prescription opioids, (12) casino games, (13) lotteries, (14) video games, (15) betting, and (16) online pornography. Some of these are medicinal products (i.e. products regulated as medicines), and some are non-substance-based products with addiction potential, the "production" and offer of which is regulated in special laws if they are regulated at all.

These products only form a homogeneous group insofar as the gap between current and desirable regulation is relatively small. Lotteries and betting are already strictly regulated. For these two products, the potential for optimisation is to be found at an already high level of regulation. Especially as casino games are already subject to a comparably strict regulatory mix. Nonetheless, regulation in this area should be more specifically targeted. Video games and online pornography are barely regulated. The FCAND considers this situation as generally appropriate, but it sees some potential for optimisation, particularly to guarantee age-appropriate consumption.

66 For example, the possession of a maximum of 10 grams for own consumption is allowed, which is why the police cannot confiscate such small quantities (tinyurl.com/5efsjv6j).

Conclusion

In accordance with the risk-sensitive approach to psychoactive product regulation developed in this report, the FCAND believes that the current situation uncovered by the analysis in this chapter is incommensurate with a coherent approach to regulation that is guided by the overarching regulatory principles outlined in ► Chapter 5 of this report. The discrepancy between over- and underregulated products should be reduced. Doing so requires:

a) stricter regulation of previously underregulated products, and
b) abolishing one-sided prohibition regimes for banned products and replacing them with comprehensive regulations.

Chapter 8 sets out corresponding recommendations for practical implementation.

8. Assessment and recommendations

This report documents the historically evolved, incoherent way in which psychoactive products are regulated in Switzerland. What steps, then, can be taken to move beyond the status quo and towards a coherent approach to the regulation of all psychoactive products? From the FCAND's perspective, it is critical to ask what should be done today in order to reap the benefits in 10 to 20 years (and to avoid the costs resulting from remaining in the status quo)? Doing so is about striking the optimal balance between individual, social and economic freedoms.

8.1 Assessment

The FCAND concludes that there is a need for action on all six regulatory dimensions.

As an overarching principle, in a liberal society, the State's responsibility to protect its citizens should be limited by the respect for individual freedoms and civil liberties as far as possible. Restrictions on individual consumption of psychoactive substances in particular should therefore be minimal. Restrictions on consumption in specific places or settings/situations should be imposed if they are suited to protect others who are negatively affected by the consumption of psychoactive products (e.g. from secondhand smoke). Restrictions on consumption at specific times should be considered in the area of gaming and gambling, for example. However, in general, the FCAND is convinced that restricting the availability of psychoactive products is better suited to achieving the goal of a risk-sensitive regulation. Restricting availability targets the distribution level of markets for psychoactive substances and may involve regulations on the number of sales outlets, opening hours, etc.

In terms of **production** the FCAND sees a moderate need for adaptation. Some regulation appears appropriate, but measures should be implemented with caution. A licensing requirement for the production of tobacco products, e-cigarettes and alcohol seems advisable. Raising quality requirements for tobacco products, e-cigarettes and alcohol, but also, among others, video games, would make regulatory mixes more risk-sensitive. For new psychoactive products entering the market, a reversal of the 'burden of proof' should be introduced in which it would be the developer's/producer's responsibility to prove the limited risks new products pose.

The FCAND sees the greatest leverage and significant need for action at the level of **distribution** – which serves as a hinge between production and consumption. The introduction of licensing requirements (that take into account local conditions) for the sale of alcohol and tobacco products should be considered,[67] as well as a requirement for training sales staff in matters of addiction prevention and youth protection, and restrictions on the numbers of sales outlets in a given area. Online sales channels need to be regulated much more strictly. The possibilities to enforce age limits for the provision of gaming and pornography to minors should be enhanced. The number, structure, concentration and opening times of sales outlets should be systematically reviewed and adapted for all psychoactive products. The requirements relating to information (in writing) for consumers (declaration of ingredients and information on consumption risks) should be made more stringent across various products, and in isolated cases, the same goes for the duty to inform customers verbally as well as efforts to approach people with problematic consumption in a targeted way during the sales process. Warning labels and packaging requirements should be considered for various legal products and should be made mandatory if previously banned products are regulated. It must be a lot easier for consumers than it currently is to find factually correct information about the ingredients in a product and the risks associated with their consumption. To achieve this, the government must formulate unambiguous requirements for those wanting to sell psychoactive products.

The **marketing** and advertising of psychoactive products is seen as generally problematic and the FCAND deems it appropriate to introduce tighter restrictions on advertising including, in some cases, bans on advertising for psychoactive products. The future regulatory mixes of currently illegal products should involve an extensive ban on advertising once they are regulated. In general, the principle should be established that advertising of psychoactive products should only target persons who already use a product and even under this requirement should be severely restricted. A complete ban on advertising that aims to broaden demand for psychoactive products by convincing non-users to take up consumption is, in the FCAND's view, not only advisable but a requirement for risk-sensitive regulation.

The model and level of **taxation** of psychoactive products should be consistent across different products. Coherent taxation would divert funds away from the black market for previously prohibited products and towards the general public. The earmarked use of tax revenues to prevent and reduce addiction should be bolstered. For the regulation of previously illegal substances, the level of taxation should be comparable to products already taxed. As a general rule, the level of taxation should be in accordance with the harmfulness of the product. The costs-by-cause-principle, whereby taxation should cover the harm caused by those marketing the product, should be coherently applied. This requires a sensible earmarking of tax revenues. In terms of policy implementation, an extension of Art. 131 Cst. should be considered. This review should also look at the creation of a fund for addiction prevention and support, modelled on the existing model for earmarking revenues from taxing alcohol (i.e. the model to distribute the so called "alcohol tenth, see ▶ Chap 4.4, regulatory tool 20) .

In terms of **pricing,** the FCAND sees potential in fixing a minimum price and introducing a ban on discounts for psychoactive products. This should also be established accordingly when regulating currently illegal substances. Furthermore, the FCAND identifies potential in the introduction of a pricing model for all psychoactive products similar to the models already existing for spirits and gambling, with a minimum price that takes account of the product's potential for harm. The rest of the price could then be determined freely. The level of taxation would be directly proportional to the profit made.

67 For the sale of tobacco products this is already the case in a number of cantons, such as Vaud and Geneva (for details see www.bag.admin.ch/bag/de/home/strategie-und-politik/politische-auftraege-und-aktionsplaene/politische-auftraege-zur-tabakpraevention/tabakpolitik-kantone.html).

In terms of **regulating consumption,** the FCAND promotes an approach that accepts and tolerates that consumption of psychoactive products is part of our society. It is important to recognise the basic right of all individuals to make autonomous and self-determined decisions about their consumption of psychoactive products. But autonomy and self-determination are only possible if everyone – regardless of their socioeconomic situation – has the requisite resources, health literacy and risk competence to make such decisions. Society, therefore, has an obligation to guarantee the fair distribution of health resources and to promote health literacy (cf. Art. 2 para. 3 Cst.). Measures to promote health equity are essential to this. They should especially target vulnerable groups – in particular those who have low health literacy owing to their age, life history and/or life situation. The FCAND recommends regulating risks in such a way that as many vulnerable people as possible are comprehensively protected, while those who are not at risk should be restricted as little as possible. Obviously, this goal is only ever approximately achievable. The fact that some members of society will develop health problems as a result of psychoactive product use is unavoidable, even if regulatory policies seek to strike the optimal balance between all interests involved. Otherwise, civil liberties would have to be radically subordinated to health protection. Consumers developing health problems do so, therefore, also because of regulations that do not meet their needs, but which are chosen because the majority of those who are not directly affected should not have their freedom restricted by strict and comprehensive regulations. Providing health and social support to those affected is society's responsibility. The principle of solidarity must remain at the heart of health and addiction policy.

In terms of **implementation,** the FCAND recommends pursuing the approach taken in the regulation of cannabis for dealing with other psychoactive products that are currently prohibited. Specifically, this means conducting pilot projects aimed at gathering scientific evidence about how risk-sensitive approaches to regulating such products can be developed and to evaluate measures to avoid or reduce the unintended consequences of a transition from a black market to a regulated one. The insights from such pilot projects enable policymakers to develop evidence-based and practice-tested regulatory mixes for currently prohibited substances that could also be acceptable to a majority of the public and could, if challenged, win a majority in a popular vote.

In a nutshell

In summary, based on the analysis in this report, the FCAND supports an approach to the regulation of psychoactive products that enables legal access to all psychoactive products, but avoids creating incentives to encourage consumption. In other words:

- The production (including import and wholesale) of psychoactive products should be restricted in accordance with the health risks emerging from a particular product.
- The consumption of psychoactive products should only be restricted to the extent necessary to protect vulnerable groups and affected third parties.
- The distribution and marketing of psychoactive products should be restricted as strictly as is necessary to avoid the creation of incentives to promote their consumption.

8.2 Recommendations

The FCAND concludes with three recommendations.

Recommendation 1
The regulation of psychoactive products should be evidence-based, risk-sensitive and coherent. Critically reviewing current regulatory policies in this respect is essential.

Evidence-based means that
- policies should take into account the current state of scientific knowledge;
- policymakers should, when drafting policies, take into account the fact that scientific evidence is often limited, always preliminary and dynamic;
- policymakers should consider developing regulatory policies by conducting pilot projects of regulation and scientifically evaluating them to design policies that allow for a gradual scale-up of newly developed regulatory mixes, and to review their impact on markets for psychoactive products on an ongoing basis.

Risk-sensitive means
- regulatory policies should be systematically oriented towards the actual risks posed by psychoactive products (at the microsocial and the macrosocial level ▶ Chap. 3);
- policymakers should acknowledge that the consequences of a change in policies in complex environments can never fully be foreseen; such change should, therefore, always be understood as the application of well-tried policy instruments (or "regulatory tools" in the nomenclature of this report) in new contexts;
- the application of an incremental approach to policymaking that observes the (desirable and undesirable) effects of regulation and is designed in a way that allows for continuous optimisation of policies.

Coherent means
- that regulation should be consistently aligned with the overarching regulatory guiding principles postulated in this report (▶ Chap. 5);
- that policies should treat different psychoactive products in a similar way according to their risk-profile;
- that policies should apply individual regulatory tools in a similar way across different psychoactive products (▶ Chap. 4 and 6).

The FCAND encourages policymakers to assess the current state of psychoactive product regulation in Switzerland against the backdrop of this report in order to determine which legislative steps can and should be taken to achieve evidence-based, risk-sensitive and coherent regulation of all psychoactive products.

Recommendation 2
The regulation of psychoactive products should balance conflicting societal interests transparently, according to an overarching concept.

Regulatory policies should not be ideological, moralistic, or paternalistic, but should be based on an objective analysis of actual risks and challenges. They should forego a one-sided resolution of conflicting objectives (e.g. between economic freedom and health protection, or between a laissez-faire approach and "nanny-state-solution"). Instead, they should recognise the need to find compromises that balance all legitimate interests, namely: freedom of informed choice; health and youth protection; safety; proportionality and comparability; prosperity; and an evidence-based approach (▶ Chap. 5).

Because regulation is the attempt to find the best possible balance between legitimate, yet conflicting, interests, the risks emerging from psychoactive products can never be completely eliminated. The restrictions necessary to do so would be disproportionate, especially in terms of restriction on civil liberties. Every person, therefore, needs and deserves specific support where the State's responsibility to protect its citizens from harms to their health falls short.

Federal and cantonal legislation already has many proven instruments at its disposal that can be used to develop regulatory mixes tailored to the specific risk profiles of different psychoactive products. These should guide efforts to overcome the current dichotomy of legal and illegal substances, which is often not justifiable outside of its historic normative context.

Regulations should, therefore, be designed with a sense of proportion. Policymaking should aim to regulate those areas (in terms of individual products as well as in terms of making use of regulatory tools across different products) in which the greatest leverage can be expected. The benefits of regulation must outweigh its costs in terms of tax revenues spent, value added foregone and civil liberties restricted. In particular, regulation should be suited to take pressure off enforcement authorities in order to be deemed as a model of success.

Recommendation 3

The regulation of psychoactive products should transcend the static dichotomy between legal and illegal substances in favour of a dynamic risk regulation paradigm.

The current regulatory landscape does not meet the demands of coherent and proportionate legislation. Nor is it suited to meet the challenges to individual and public health as well as the economic challenges that emerge from the existence of psychoactive products in our society. Historically, the focus of regulation was on changing the behaviour of individuals. However, the assumption that bans deter people from using or consuming psychoactive products has proven untenable.

The FCAND recommends making use of the available regulatory tools in a risk-sensitive, tailored way, which reinforces the freedom of individuals to informed choice and takes into account their vulnerability to the effects of psychoactive products as well as to underlying forces of the market. It is the State's responsibility to provide citizens – regardless of their backgrounds, education level and their social capital – with the necessary information and skills to make decisions about their consumption of psychoactive products.

The production of psychoactive products must be regulated to ensure product safety. It is the State's responsibility to ensure the existence of a market environment that enables consumers to make informed choices and to realistically assess the associated short- and long-term risks.

The marketing, distribution and taxation of psychoactive products must be regulated more coherently and more stringently across various products than is the case today. Those supplying the market with psychoactive products – which is in itself a legitimate activity – will always have incentives to promote consumption of their products – which becomes a questionable motive as soon as public health is put in danger. It is the State's responsibility to create a market environment in which these incentives are as small as possible. Doing so, however, should not restrict the freedom of individuals more than necessary. These freedoms include the freedom to consume and the freedom to abstain, as well as freedom from dependence on psychoactive products. In case of doubt, health protection and civil liberties should be placed above economic interests.

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