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Research Article

Self-Regulation: Leveraging Advantages, Mitigating Drawbacks and Contemplating its Use for Soft Narcotics Market

Antonina Bobkova[1*], Pavlo Liutikov[2], Mykhailo Shevchenko[2], Nataliya Kantor[3], Vladyslav Lipynskyi[4]

[1]*Chief Research Officer of the Research Laboratory of Public Security of Communities, Donetsk State University of Internal Affairs, Ukraine*
[2]*Department of Public and Private Law, University of Customs and Finance, Ukraine*
[3]*Department of Administrative and Information Law of the Educational and Scientific Institute of Law, Psychology and Innovative Education, Lviv Polytechnic National University, Ukraine*
[4]*Head of the Educational and Scientific Institute of law and international legal relations, University of Customs and Finance, Ukraine*

[*]*Address Correspondence to Antonina Bobkova, E-mail: bobkova50@gmail.com*

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Abstract

Background: Relying on scientific sources and legal documents reflecting the advantages and drawbacks of self-regulation, as well as ways to mitigate them and ensure proper functioning of the self-regulation, the article determines the best scenarios for the development of market regulation, within which the most positive aspects of the delegation of regulatory functions to self-regulatory organizations are retained and the limitations and risks inherent in self-regulatory activities, as well as the issues of democratic legitimacy of self-regulation are mitigated.

Methods: The authors use a set of methods of scientific research required for accomplishing these tasks, which includes literature review, covering conceptual scientific material on advantages and drawbacks of self-regulation with delegated powers, interpreting and making generalizations of scientific viewpoints on these matters, occasional manifestations of normative juridical approach and making hypothesis on those premises regarding the most advisable policies in relation to further development of market regulation, including systemic improvement of structure and activities of self-regulatory organizations, as well as, alternatively, replacing self-regulatory organizations with a regulatory agency with a special status.

Results: It was concluded that the best scenarios for the development of market regulation, within which the most positive aspects of the delegation of regulatory functions to self-regulatory organizations are retained and the restraints of and risks inherent in self-regulatory activities are:

1. Systemic improvement of structure and activities of self-regulatory organizations;
2. Replacing self-regulatory organizations with regulatory agency with a special status.

Conclusion: The authors maintain that the latter model could be deemed most suitable for self-regulation in the market of pharmaceuticals as well as of the soft drugs, providing simultaneously a sufficient level of protection against abuse related to production and advertising of soft drugs, to which their users are particularly sensitive, as well as promoting the involvement of specialists with the appropriate level of expertise in establishing rules for the circulation of soft drugs along with healthcare and public order experts, who are able to develop reasonably balanced industry standards in this area.

Keywords: Advantages and drawbacks of self-regulation; Entrepreneurship; Market regulation; Pharmaceutical industry self-regulation; Self-regulation in soft narcotics market; Subjects of entrepreneurial activity; Self-regulatory organizations

Introduction

Modern economic policy is aimed at achieving the highest feasible degree of deregulation, democratization and decentralization of market regulation while simultaneously ensuring the inevitability of responsibility for unscrupulous business practices that lead to distortion of competition and harm consumers. Entrusting regulatory and oversight powers to self-regulatory organisations is widely recognized as one of the well-established tools for achieving this goal. The self-regulatory system brings the authority to make regulatory decisions closer to the specialists who are most familiar with the relevant market mechanisms in terms of understanding the patterns and peculiarities of their operation. At the same time, the bureaucratic apparatus of government authorities, which often does not have sufficient expertise in market operations, is dismissed from

regulatory decision-making, empowering self-regulatory organizations to provide utmost support to the legitimate business activities of market operators. However, there is ample support for the claim that the deployment of a system of market self-regulation with the delegated regulatory powers is not the right step due to its inconsistency with the fundamental principles of public administration. This skepticism rests on the fact that, regardless of what is the conceptual framework for structure and activities of self-regulatory organizations, unavoidable are problems of these institutions related to a democratic mandate to manage public affairs, close to the arbitrary choice of industries and professions for introduction of self-regulation in them, as well as issues related to excessive complexity of ensuring due representation of markets participants, anti-competitive abuses and cartel-like arrangements of self-regulatory organizations in service of their own agendas at the expense of public-interest objectives. These problematic aspects entail a high risk of a vacuum of legitimacy of self-regulatory organizations and responsibility of the government for the state of performance of delegated regulatory and enforcement powers, as well as a high risk of anti-competitive abuses, which call into question the necessity of these self-regulating superstructures over regulatory agencies, which themselves may well be equipped with markets experts or practitioners in order to achieve the highest possible quality of regulatory policy while simultaneously minimizing the interference of the government in their activities.

In light of the foregoing, relying on scientific sources and regulatory documents reflecting the advantages and drawbacks of self-regulation, as well as indicating ways to mitigate them and ensure proper functioning of self-regulation, the best scenarios for the development of market regulation should be determined, within which the most positive aspects of delegation of regulatory powers to self-regulatory organizations are retained and the constraints and risks inherent in self-regulatory activities, as well as the issues of democratic legitimacy of self-regulation are mitigated. This goal makes it necessary to fulfill the following scientific tasks:

(1) To outline the general idea of substantial aspects and advantages of self-regulation with delegated powers over state regulation;

(2) To explore the risks and constraints of self-regulation;

(3) To observe the ways to mitigate the drawbacks of self-regulation, proposing contours of a model that could be appropriate for soft narcotics market self-regulation.

Methodologies

A set of methods of scientific research required for accomplishing these tasks includes literature review, covering conceptual scientific material on advantages and drawbacks of self-regulation with delegated powers, interpreting and making generalizations of scientific viewpoints on these matters, occasional manifestations of normative juridical approach and making hypothesis on these premises regarding the most advisable policies in relation to further development of market regulation, including systemic improvement of structure and activities of self-regulatory organizations, as well as replacing self-regulatory organizations with regulatory agency with a special status.

Results and Discussion

Delving into substantial aspects and advantages of self-regulation with delegated powers over state regulation

Starting the study with comprehending the essence of self-regulatory organizations as institutions endowed with powerful powers to regulate markets, as well as to establish and ensure the implementation of rules of professional activities, with reference to Porter and Ronit, it is to be noted that self-regulation is defined as an arrangement involving procedures, rules and norms that constrain the conduct of private actors, when the actors themselves develop the rules rather than the state [1]. In other words, self-regulation can be defined as the process whereby an organisation voluntarily observes and governs its own adherence to their code of ethics, rules, regulations or standards, rather than have a third-party such as a governmental entity to regulate and enforce those standards. In addition, professional self-regulation is when a professional body or a committee under the organisation regulates over their members' ethics, practice and act to the standards of which they are required to maintain their competency and professionalism [2].

The main premise behind self-regulation is that the industry has a strong incentive to police itself in order to maintain its quality [3]. In its most complete form, self-regulation encompasses the authority to create, amend, implement and enforce rules of conduct with respect to the entities subject to the SRO's jurisdiction and to resolve disputes through arbitration or other means. Typically, this authority is derived from a statutory delegation of power to a non-governmental entity [4]. One of the most comprehensive and well-elaborated definitions of self-regulatory organizations among statutory instruments could be found in Article 1 (1) (3) of the Law of the Republic of Kazakhstan No 390-V of 12 November 2015 on self-regulation), according to which self-regulatory organization is a non-profit organization in the form of an association (union), non-governmental organization or other vehicle established by the statutory instruments or vested with regulatory powers according to them, uniting business entities or professionals on a voluntary or mandatory basis on the principle of commonality of activity, industry, specific types of business activity, market of produced goods and services [5].

The scope of principal regulatory and enforcement activities of these organisations commonly encompass: Rule-making-establishing self-regulatory rules (standards) applicable to members such as those for their conduct, products, transactions and internal control, and making these rules known; accreditation-formal and independent verification that a person or an institution meets established

quality standards and is competent to carry out respective professional or business activities; monitoring and inspecting members-conducting inspection and monitoring of members' business activities, compliance with laws and regulations, as well as internal control systems; disciplinary actions-taking disciplinary actions such as a reprimand, fines, suspension or limitation of membership, as well as expulsion of members violating laws or self-regulatory rules; improving the proficiency of members-granting accreditation of certain categories of officials or employees responsible and raising their proficiency through capacity building; adjudication and mediation-official decision-making about the consequences of non-compliance or settlement of disputes between members and their customers (Figure 1) [6].

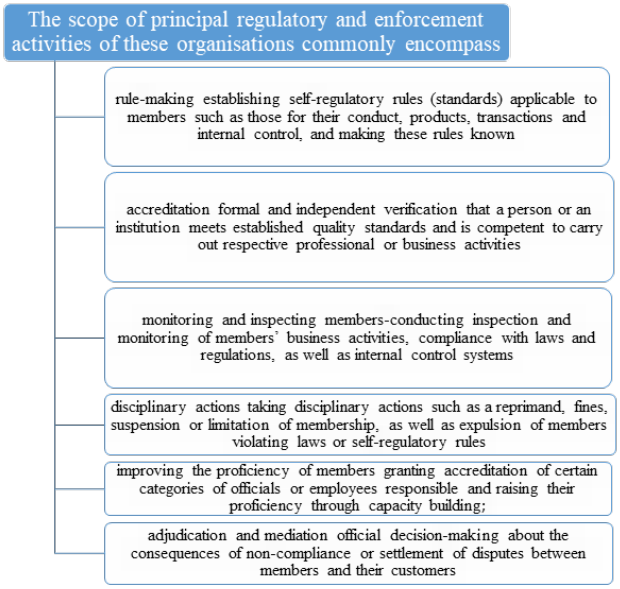

Figure 1: Scheme 1: The scope of principal regulatory and enforcement activities of these organisations commonly encompass

Stating the factors of the expediency of granting regulatory powers to self-regulatory organizations in comparison with regulatory agencies, government experts and the scientific community point to the following key advantages of market and professional self-regulation.

Primarily, self-regulatory organizations are close to their markets and market users and can tailor their rules and surveillance techniques to the specific characteristics of their markets. Self-regulatory structure may generate more thoughtful and precise regulation by bringing industry experts into the regulatory process. Industry participants will always know more about their operations and business model than more distant government regulators [7]. It is a commonly held perception that self-regulatory organizations have the experience, resources and commitment to play a constructive role in assisting statutory regulators with examining increasingly complex issues and to arrive at creative and effective solutions enhancing the health of markets and the protection of customers [8]. Such delegation is advantageous from a management and standard-setting perspective as it can reduce inefficiencies associated with third-party regulation, and provide autonomy for professionals, allowing them to enhance their credibility and legitimacy in the eyes of the public [9]. Moreover, in light of their total immersion in operation of the respective markets, they are believed to have the experience, resources and commitment to balance the benefits of their regulation relative to the costs and avoid unnecessary regulatory costs [8].

Secondly, self-regulatory organizations possess flexibility to adapt their regulatory requirements to a rapidly changing business environment. Conversely, the reaction of core government regulators to market developments are typically delayed due to the bureaucratic restrictions placed on agencies [10]. Likewise, Priest acknowledges that one of the arguments in favour of self-regulation is that it is flexible. The rules can be quickly and easily adjusted to meet changing circumstances, in contrast to the relatively slow and ponderous legislative process of government. The industry and its self-regulatory organizations are not subject to some of the other constraints of government, including budget and personnel controls. Furthermore, the author notes that the self-regulatory organizations can therefore reorganize or respond quickly by hiring staff as needed and paying competitive salaries to retain long-term expertise [11].

Thirdly, one traditional rationale for self-regulation is that close industry participation generates compliance benefits because the industry may be more likely to comply with internally generated rules than externally imposed ones. At the least, industry participation in the rulemaking process likely increases the perceived legitimacy of any rule imposed by a regulator [7].

Moreover, self-regulation empowers the actors who are members of a profession or occupation and thereby is believed to reduce some of the costs associated with state-driven third-party regulation. The problem of information costs limits a government's regulatory effectiveness since it is usually too costly for the state regulator to obtain complete information on all matters it seeks to regulate. Mysicka aptly notes that self-regulation can be a smarter solution when a state-organized regulator lacks the financial means or political willpower to regulate in the best interests of the public and at the lowest cost possible [9]. The regulation is "off the books" of government and there are no additional civil servants assigned to regulatory tasks. Furthermore, self-regulation can allow the government to transfer potential liabilities for regulatory actions to the self-regulating organizations [11].

The factors underlying the advantages of self-regulatory organizations compared to regulatory agencies include, first of all, the involvement in its implementation of the most competent and experienced specialists from the internal environment of the market or profession with the greatest amount of actual knowledge about their functioning and chosen by the business or professional community itself. In addition to a high level of regulatory quality, this can increase the rate of compliance with relevant rules and

standards due to their internal origin, voluntary compliance with regulatory requirements, and the ability of officials of self-regulatory organizations because of their close connection to the industry and technical knowledge to quickly and accurately identify and investigate the circumstances of violations of industry standards. Self-regulatory organizations also ensure the flexibility of self-regulation, adapting market rules and standards to market developments, without being bound by bureaucratic restrictions placed on government regulators, which make it impossible for them to react in a timely manner to the rapidly changing business environment. In addition, self-regulation empowers and places regulatory responsibilities, as well as financial burden on market participants rather than the government regulators, reduce some of the costs associated with state-driven regulation, requiring obtaining and processing immense amounts of information while examining increasingly complex characteristics of markets.

Exploring risks and constraints of self-regulation. Democratic legitimacy, anti-competitive agreements, regulatory capture and additional bureaucracy

Nevertheless, there is overwhelming evidence and growing support for the notion that the positive aspects of vesting self-regulatory organizations with delegated regulatory powers and the sources of their potential to provide an optimal environment for the activities of market participants are accompanied by factors inherent in the nature of self-regulatory organizations that call into question their democratic legitimacy as subjects entrusted with administrative powers, as well as negatively affect their ability to make high-quality regulatory decisions from the point of view of promoting fair economic competition, protecting the interests of consumers and ensuring the inevitability of the responsibility of members of self-regulatory organizations for their violations of market rules.

It seems reasonable to begin the research from giving considerations of a conceptual nature regarding the self-regulatory organizations with delegated regulatory powers, which call into question the democratic and constitutional basis of their activities, as well as the possibility of ensuring their representativeness.

In this context, first of all, there are solid grounds to assert that the legitimacy of self-regulatory organizations, whose boards are not formed by democratically elected government officials or those ones appointed by them (the cabinet, heads of ministries, etc.) is questionable. The scope of application of regulatory acts made by a self-regulatory organization for the performance of its delegated powers covers not only its members, but also includes consumers, which is the basis for the conclusion that the rights and obligations of an unlimited circle of persons are determined by officials of self-regulatory organizations who do not have any personal mandate to exercise power in this way. Moreover, it is excessively difficult to ensure a due representation of the participants of the relevant markets, since the only fair criterion for determining the weight of the voice of members of self-regulatory organizations is their market share, and its correct measurement is not an easy task. Any other framework for activities of self-regulatory organizations may lead to artificial distortion of the dynamics of market development or other consequences associated with the acquisition of unjustified advantages by only a part of the members of self-regulatory organizations. Furthermore, the dominant position of enterprises with a significant market share can lead to similar consequences to the detriment of enterprises with a smaller market share and cause the emergence of a phenomenon of competition-wise favoritism.

Competition-related argument against full-fledged self-regulation draws on the considerable possibility of self-regulation to be dominated by larger or long-established firms. According to Priest it is those firms that have the resources to organize and run the self-regulatory organizations. The author assumes that the controlling members may be immune from the enforcement and discipline activities of the self-regulatory organization and may even use them against dissident members who seek a greater role. The structure may therefore discriminate against certain industry members, particularly smaller firms or practitioners in certain areas [11]. Edwards as well puts forward the view that particular groups within self-regulatory organizations may also use their regulatory power in anti-competitive ways by crafting regulations that disproportionately burden their competitors. In particular, regulations imposing fixed costs that do not scale with firm size may have more significant effects on small firms [7].

Much of the current debate also revolves around the question of whether the self-regulatory system is well-suited for protection of customers and serving other public interest objectives rather than capturing regulatory powers in service of agendas of industries themselves. This phenomenon is often called “regulatory capture” or “cartelization”.

A. Smith in his ‘Inquiry into the Nature and Causes of the Wealth of Nations’ famously declared that people of the same trade seldom meet together, even for merriment and diversion, but the conversation ends in a conspiracy against the public, or in some contrivance to raise prices [12]. In light of this, conventional wisdom has it that the chief concern with self-regulatory organizations is that the incentive structure driving the development and political empowerment of these institutions can lead their members to develop rules that promote their own economic interests, often at the expense of public-interest objectives [9]. Likewise, Edwards asserts that one of self-regulation’s major dangers is that it may give industry members the ability to reduce competition and to raise their own profits, deriving these opportunities from being vested with power to both make and abide by regulations at the same time. This problem, known as cartelization manifests itself as the tendency for industry to protect itself from external competition or regulation that might be social welfare enhancing [7]. The regulatory capture could appear in multiple and diverse subtle manifestations.

In particular scholars have expressed concern that such a close relationship could lead to sympathy from the regulator or monitor toward the organization that engaged in misconduct as well as "lax enforcement" [13].

Demonstrating the general public skepticism about the inclination of self-regulatory organizations to evenly distribute their efforts between accomplishing the public good and the short-term financial interests of the industry, Fair Canada (Canada's Investor Rights Advocate) confirmed that, notwithstanding the statutory backing of the public interest mandate and obligations the Canadian Investment Regulatory Organization, the inevitable conflict of interest inherent in adopting an self-regulatory model remains a controversial issue. According to the study, fewer than half of the public trusts that self-regulatory organizations will make decisions that are in the public interest; 76% believe that conflicts of interest among board members of self-regulatory organizations occur frequently and are not declared or eliminated before important decisions are made; and 60% of people believe that the current investment industry regulation model is not working and securities regulators need to be more directly involved [14]. Moreover, the data yielded by the Mutual Fund Dealers Association of Canada and represented by Adesanya provide convincing evidence that enforcement actions taken by the self-regulatory organizations against investment firms or senior executive management of such member firms are very uncommon. The top management of member firms is not held accountable for shortcomings in supervision and compliance processes. In 2021, only 2 of the 91 proceedings commenced by the MFDA included supervision allegations, while 5 of the 27 disciplinary proceedings commenced by the Investment Industry Regulatory Organization of Canada included supervision allegations. As a result, business conduct and investor protections remain substantially unchanged and unimproved [10].

Skepticism regarding the strategic advantages of self-regulatory organizations over state regulators also rests on their insufficient justification, in particular, on idealistic ideas about the importance of the internal origin of market rules for the prospect of their compliance. Edwards' findings lend support to the claim that self-regulation does not ensure complete compliance. As Edwards observes, some evidence indicates that broker-dealer firms may not feel morally bound to comply with industry-made rules. For example, H. Markopolos, the financial analyst that repeatedly tipped off the United States Securities and Exchange Commission about Madoff's fraud years before the record-shattering Ponzi scheme collapsed, reports that after he learned the industry's regulations, he "saw them broken every day, every hour; and everybody knew about it and nobody seemed to care" [7]. Moreover, the involvement of the business entities and professionals in regulation, resulting in a higher level of compliance, could be arranged *via* their participation in direct regulation by government through consultation or co-development of regulations through such mechanisms as regulatory negotiation [15].

As regards the potential of self-regulatory organizations for easier access to industry expertise there are compelling reasons to argue that it does not guarantee that self-regulatory organization will deploy that expertise effectively in overseeing its members. In fact, it is assumed that one danger is that expertise will be used to craft easily evaded, loophole-ridden rules [16].

It is also noteworthy that, given the afore-mentioned risks and limitations, whether or not self-regulation is ultimately less costly than direct government regulation is debatable as the regulation that limits competition can also raise prices and have distributional consequences that place a disproportionate burden on poorer and disadvantaged consumers [11]. Scientific literature and analytic publications indicate that some skeptics doubt that the self-regulatory system actually reduces the expenses associated with oversight. Rather, as Edwards maintain, inserting the self-regulatory structure may simply add another layer of oversight and increase overall costs. To function effectively, the author along with like-minded skeptics point out that any self-regulatory organization will undoubtedly need to create a bureaucracy similar in size and scope to the organization that would be created by a government regulator [7]. Furthermore, the combined regulatory burden of the social costs of self-regulation and the costs of government oversight may not be less, however, than the costs of direct regulation by government alone [17].

On those grounds, it is to be noted that against the background of the sources of the potential of self-regulatory organizations, there are reasons to consider the nature of self-regulatory organizations incompatible with the constitutional and democratic principles of organization and exercise of power [18]. This could be substantiated by the fact that the personal composition of their management bodies is not formed by democratically elected state institutions or officials appointed by them (by cabinet, heads of ministries, etc.), whereas a representation of the participants of the relevant markets, which requires a correlation of their market share with the weight of their vote as members of self-regulatory organizations, is impossible to be ensured without an unacceptable risk of artificially distorting the dynamics of market operation or other consequences associated with the acquisition of unjustified advantages by only a part of the members of self-regulatory organization. In addition, there are constraints and risks inherent in self-regulatory activities, giving rise to a conflict of interests, which can negatively affect their ability to make quality regulatory and enforcement decisions from the point of view of promoting fair economic competition, protecting the interests of consumers, and ensuring the inevitability of the responsibility of members of self-regulatory organizations for their market violations. Moreover, self-regulation may not necessarily reduce overall oversight costs, potentially adding a layer of bureaucracy in addition to governmental oversight mechanisms to ensure that regulatory responsibilities are discharged properly and that the regulated markets operate in accordance with general

performance standards in the public interest [19].

These vulnerabilities of the market self-regulation concept are particularly evident in the pharmaceutical industry.

Mulinari and Ozieranski recognize that in most European countries as well as Japan, Canada and Australia, the regulation of marketing practices relies heavily on industry self-regulation in which industry trade groups are trusted to set and police the rules of appropriate industry conduct. Among these, the Code of Practice of the Association of British Pharmaceutical Industry (ABPI) is one of the best-known industry rule books. Oversight of prescription drug marketing in the UK is delegated by the medicines and medical device regulator, the Medicines and Healthcare Products Regulatory Agency. Having said that, the scientists assert that much more could be done to tighten rules about how medicines are marketed by their manufacturers. Policymakers could adopt a more probing and punitive strategy to tackling corporate wrongdoing, including investigating whether known misconduct indicates more extensive problems, and extending support for whistleblowing [20].

Likewise, the outcomes of a research by Arnold and Oakley demonstrate that 'pharmaceutical self-regulation currently is a deceptive blocking strategy rather than a means for the industry to police itself' [21].

However, the sentiment for a self-regulating system for pharma product persists. It is maintained the motivation for establishing promotion is primarily pragmatic-industry associations have the relevant expertise and willingness to establish voluntary codes of practice that set standards for ethical marketing activities and have the authority (usually through self-regulatory bodies that are independent of the associations themselves) to levy sanctions against companies that are found in violation of that code. So long as independent bodies appointed by the industry can be trusted to act in the best interests of public health, rather than the health of the industry itself, then the only debate is how best to refine pharma promotion standards and penalise those who fail to live up to them [22].

Mitigating drawbacks of self-regulation. Public participation in self-regulatory activities, their transparency and responsiveness to feedback from the market

Given the key positive aspects of the delegation of regulatory functions to self-regulatory organizations (bringing industry experts into the regulatory process, its flexibility and higher possibility of compliance with internally generated rules) and taking into account the main constraints and risks inherent in self-regulatory activities (anti-competitive abuses and cartel-like arrangements of self-regulatory organizations in service of their own agendas at the expense of public-interest objectives), one should get acquainted with the considerations of the scientific community and government experts regarding the possibility of building a model of self-regulation that would mitigate those detrimental factors as much as possible and would contribute to the leveraging the advantages of self-regulatory organizations over regulatory agencies [23].

To a particular extent, the most balanced recommendations regarding the main aspects of governing the structure and activities of self-regulatory organizations are summarized in the guidance by Competition Bureau Canada on the specific considerations that should be applied to self-regulatory organizations legislation that creates a registration, licensing and disciplinary process as well as standards of practice for members. According to these institution governments should take into account a number of specific considerations in vetting legislation that delegates authority, which include:

- Reasonable restrictions-regulatory rules should address specific, stated problems and include performance standards (if a more general mandate is granted through legislation that either creates a true self-regulatory organization or delegates legislative enforcement, the ability of an organization to exercise broad discretion needs to be qualified by a firm fiduciary obligation to operate in the public interest);
- Competition objectives-unnecessary or overly restrictive regulation can be avoided if a self-regulatory organization is specifically tasked with promoting competition as one of its primary objectives;
- No regulatory offsetting-a regulatory environment should promote a market framework in which all firms thrive or fail on the basis of their ability to meet consumers' demands with the best combination of price and quality;
- Impartiality-the governing body must broadly represent all aspects of the profession being regulated (no single class of persons should dominate and the perspectives of all members and the general public should play a governance role);
- Transparency-it is particularly important that independent public membership acts as a counterbalance to professional representation in the management;
- Complaint handling-in reviewing the delegation of statutory powers, there should be a complaint handling or registration system in place along with independent review of complaint handling decisions; and
- Periodic assessment-if an organization is delegated statutory powers, there should be mandatory reviews of its performance, particularly with respect to how it handles complaints and its efficacy in serving public-interest objectives (competition Bureau of Canada, 2005) [24,25].

Highlighting the most common and effective accountability mechanisms for self-regulatory organizations it is to be noted that the current literature abounds with examples of recognition of particular weight given to public participation in self-regulatory activities, ensuring the public interest, fair competition and enhancing transparency of self-regulatory

process [26].

For instance, Edwards observes that amplifying the public's voice trough including public representatives in self-regulatory processes may alter the behavior of self-regulatory organizations, mitigating the regulatory capture and providing a countervailing force to balance against industry interests [7]. In other words, according to Dombalagian, self-regulatory organizations could more credibly commit to incorporating the public's voice in their governance by moving the appointment process for public representatives outside of the organization [27]. However, appointing public representatives without significant industry connections may come at some cost. Without some connection to the industry, public governors may lack the expertise to function effectively in their role. Still, it seems likely that sufficiently qualified candidates without the sorts of conflicts and relationships detailed above may be found. For example, former state securities regulators with sufficient expertise and without deep, entangling industry connections could be suggested, as well as investor advocates with a history of successfully challenging the industry for abusive sales practices might make strong candidates for an organization devoted to investor protection [7].

Another way to manage potential conflicts of interest in activities of self-regulatory organizations is through openness or complete disclosure. As Adesanya mentions that Canadian self-regulatory organizations, overseeing investment dealers, mutual fund dealers and trading activity on Canada's debt and equity marketplaces, in order to ensure transparency, offer complete, accurate, and timely disclosure of the compensation of annual reports covering the previous year's performance, financial results, compensation of board members and management team, disciplinary actions, execution of sanctions and other significant information [10].

Maintaining feedback by the self-regulatory organization with consumers of goods and services of the relevant market, including accepting and processing their proposals regarding the directions of development of regulatory policy, is also considered one of the best practices for improving the quality of the latter and bringing it closer to real public demand [28].

This is demonstrated by the United Kingdom Committee of Advertising Practice and Broadcast Advertising, which keep their codes under review and welcome new evidence on where they may need to offer additional protection, where existing protections may no longer be necessary or proportionate or where other regulatory action might be warranted. These institutions are committed to:

- Acknowledging receipt of all evidence sent to them,
- Receiving and reviewing all evidence fairly, impartially and with an open mind,
- Responding formally to significant pieces of evidence, and
- Keeping significant evidence on file, even if it does not on its own merit immediate action by Committee of Advertising Practice and Broadcast Advertising [29].

It is equally noteworthy that, as Birdthistle and Henderson maintain, the issue over unpaid awards matters because it cuts to a core premise behind self-regulation: Self-regulation works well if the industry bears the costs of its misbehavior [30]. For instance, according to Article 28 (1) of the Law of the Republic of Kazakhstan on self-regulation a self-regulatory organization applies one or more of the following methods of ensuring property liability of its own and its members to consumers by means of:

1. Payments from the compensation fund;
2. Civil liability insurance;
3. Holding its members liable and recovery of damaged from them, etc. [5].

A radical alternative to the systemic improvement of the concept of self-regulation is the concentration of regulatory powers within the purview of the regulatory agency and the reduction of the activities of self-regulatory organizations to standardization on a voluntary basis with only the reputational value of their compliance (the possibility of declaring membership in a self-regulatory organization and fulfilling its standards as a competitive advantage) [31]. Dombalagian among other scholars noted the trend for replacing self-regulatory organizations with statutory regulator (e.g. United Kingdom Financial Services Authority), legislatively chartered self-regulatory organizations or quasi-SRO membership organizations, combining government appointments and industry representation, as well as deriving their funding from a statutory levy on broker-dealers, rather than membership dues and service fees [27].

Conclusion

Having regard to the above considerations, it could be assumed that the best scenarios for the development of market regulation, within which the most positive aspects of the delegation of regulatory functions to self-regulatory organizations are retained and the restraints of and risks inherent in self-regulatory activities are:

1. Systemic improvement of structure and activities of self-regulatory organizations;
2. Replacing self-regulatory organizations with regulatory agency with a special status.

Systemic improvement of structure and activities of self-regulatory organizations should ensure:

a) The inclusion of independent public representatives in the boards of self-regulatory organizations selected by the regulatory agency through competition;

b) Due representation of market participants by determining the weight of the vote of members of self-regulatory organizations according to their market share, which is adjusted on a regular basis;

c) Extending guarantees of integrity, competence and responsibility of civil servants, including anti-corruption restrictions, the obligation to submit assets declarations and other similar measures to officials of self-regulatory organizations, mutatis mutandis;

d) Full transparency of self-regulatory activities, including the availability of information about the salaries of its officials, the results of inspections, disciplinary actions, etc.;

e) Exclusion of duplication of powers of industry self-regulatory organizations and regulatory agency, retaining the latter's power to approve certain regulatory acts of self-regulatory organizations, check their activities for effectiveness, but not allowing regulatory agencies to serve as an appeal body with respect to self-regulatory common activities;

f) Automatic transfer to self-regulatory organizations of the share of taxes paid by its members, instead of levying separate contributions for regulation in addition to taxes (to avoid "double taxation");

g) Creation of a compensation fund to guarantee payments in cases of infringements by the self-regulatory organization or its members of their obligations to consumers and other persons or using similar compensation mechanisms convenient for the customers.

As an alternative, replacing self-regulatory organizations with regulatory agency with a special status should provide for, in particular:

a) Securing the majority of seats in the collegial executive body of the regulatory agency by representatives of the industry, selected by the government on a meritocratic basis;

b) Their independent financing by market participants through automatically sending to self-regulatory organizations the appropriate share of taxes paid by its members;

c) Independence of the regulatory agency with a special status from other government authorities, except in exceptional cases provided by law.

The above model could be deemed most suitable for governing the market of pharmaceuticals as well as soft drugs, providing at the same time a high level of protection against abuses, to which users of soft drugs are particularly sensitive, as well as promoting the involvement of specialists with the appropriate level of expertise in establishing rules for the circulation of soft drugs along with healthcare and public order experts, who are able to develop reasonably balanced industry standards in this area.

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Conflict of Interest

Authors have no conflict of interest to declare.

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