THE RULE OF LAW IN NEGOTIATION
CHAPTER 28
CONSUMER AND HEALTH PROTECTION

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# The Rule of Law in Negotiating Chapter 28

Analysis of the Chapter 28 – Consumer and Health Protection

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1. PROGRESS OF THE ACCESSION NEGOTIATION IN THE CHAPTER 28

Negotiating Chapter 28: Consumer protection and health protection constitute the acquis communautaire of the European Union (EU), which protects consumers' economic rights and interests in the single market and guarantees a certain level of public health protection in areas of interest to the EU. The subject of the Negotiating Chapter, in the field of consumer protection, is EU legislation on product safety and the European Union rapid exchange of information system in cases of identification of unsafe products (RAPEX), cross-border cooperation, legal protection of consumers, prohibitive measures to protect consumer interests, sale of consumer goods and related guarantees, unfair contract terms, price indicators, consumer rights, distance selling of financial services, consumer loans, misleading and comparative advertising, unfair commercial practices, time-sharing and package tours. In the field of public health, the acquis covers areas related to tobacco control, serious cross-border health hazards, including communicable diseases, blood, tissues, cells and organs, patients' rights to cross-border health insurance, medical products, cosmetics, and medical devices, as well as those related to mental health, drug abuse prevention, health inequalities, nutrition, reducing the harmful effects of alcohol use, cancer screening, a healthy environment including injury prevention, promoting safety, active and healthy aging, and European action in the field of rare diseases.

Explanatory and bilateral screening in this Negotiating Chapter was held in December 2014 and February 2015, respectively, while the Screening Report was adopted in June 2016. The report provides a satisfactory assessment of the level of alignment with the acquis in this Chapter. It does not contain criteria for opening negotiations but states that Serbia is sufficiently prepared to open negotiations in this Chapter. However, at the time of writing, Serbia's negotiating position was not adopted, although the first draft was submitted to the European Commission in late 2017, followed by comments from the Commission. In the meantime, several improved versions of the negotiating position were drafted. Still, to date, the final draft of the negotiating position for this Chapter has not been presented to the public.

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1 Screening report for Chapter 28 - Consumer protection and health protection, as of May 15, 2016
2. THE RULE OF LAW IN THE CHAPTER 28

2.1. Fundamental Rights in the Chapter 28

Consumer protection is a constitutional imperative, reflected in the prohibition of actions directed against consumers' health, safety, and privacy, as well as dishonest actions on the market\(^2\). The fundamental consumer rights are prescribed by the Law on Consumer Protection (LCP)\(^3\), which introduced the major provisions of the European consumer law, bearing in mind that this regulation simultaneously transposed 13 European Union directives in this area\(^4\). In this way, a kind of codification of consumer law was carried out instead of the sectoral approach, i.e., the possibilities for sectoral legislation in certain areas to take over the relevant norms for the consumers. According to the LCP, a consumer's property is any natural person who procures goods or services on the market for purposes that are not intended for his business or other commercial activity. A trader is a legal or natural person who appears on the market within the scope of his business activity or other commercial purposes, including other persons operating in his name or on his behalf. The Law on Consumer Protection is applied according to personal criteria, to legal relations between persons who have the status of consumers, on the one hand, or traders, on the other hand, unless the relations in question provide a higher level of protection following special regulations or laws.

As fundamental consumer right, the LCP prescribes:

- meeting basic needs - availability of the most necessary goods and services, such as food, clothing, footwear and housing, health care, education, and hygiene;
- safety - protection from goods and services that are dangerous to life, health, property or the environment or goods whose possession or use is prohibited;
- information - availability of accurate data necessary for a reasonable choice of goods and services offered;
- choice - the possibility of choosing between several goods and services at affordable prices and with appropriate quality;
- participation - representation of consumer interests in the process of adopting and implementing consumer protection policy and the possibility to be represented in the process of adopting and enforcing consumer protection policy through associations and federations of consumer protection associations;

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\(^2\) Constitution of the Republic of Serbia ("Official Gazette of RS", No. 98/2006), Art. 90


• legal protection - protection of the consumer's rights in the procedure provided by law in case of violation of his rights and compensation for material and non-material damage caused to him by the trader;
• education - acquiring basic knowledge and skills necessary for the correct and reliable choice of products and services, as well as knowledge about the fundamental rights and duties of consumers and how to exercise them;
• healthy and sustainable environment - living and working in an environment that is not harmful to the health and well-being of present and future generations, timely and complete information on the state of the environment.

As these rights, in general, have more of a character principle, they must be concretized by material rules relating to the conformity of goods and services: the duty of pre-contractual notification of consumers, the prohibition of unfair business practices and inequitable contractual provisions, as well as special consumer rights and obligations of traders, economic interest, for tourist travel, as well as for distance and off-premises contracts. The rights of consumers in financial services are specially regulated and subject to the Law on Protection of Users of Financial Services\(^5\). They include the rights of consumers, i.e., users of financial services, in pre-contractual notification, banking services, notification during the contract, the prohibition of unfair business practices and inequitable contractual provisions, as well as special rights in credit agreements.

Consumer law belongs to the corpus of private law. The primary purpose of its rules, which modify the general rules of contract law or supplement special rules regarding the manner and conditions of performing certain sectoral activities in the regulation of relations with end-users or buyers of goods or services, is to provide an asymmetric level of rights in favor of consumers. It starts from the premise that the trader or seller is an economically stronger party with a significantly higher level of information, professional and organizational resources. Therefore, although it contains mostly norms of an imperative character, consumer law belongs to the matter of civil law and, as a rule, implies protection by civil law. With this in mind, the exercise and protection of subjective consumer rights depend on the general conditions of access to justice in civil matters, issues of efficiency of court proceedings, the amount of possible costs, legal predictability of court practice, and other matters related to the functioning of justice as a whole.

Health care, an integral part of Chapter 28, encompasses several rights guaranteed to Serbian citizens by the Constitution and laws. The Constitution guarantees the inviolability of physical and mental integrity, which includes the prohibition of the application of medical or scientific experiments without freely given consent\(^6\). The Constitution also guarantees the right to health care, which includes protection of both mental and physical health, regulation of health insurance and health care, as well as financing health care from public revenues for particularly vulnerable persons (children, pregnant women, mothers, single parents, the

\(^6\) Article 25 of the RS Constitution
elderly). The Constitution also guarantees the right to a healthy environment and prohibits explicitly actions against consumer health. In addition to individual rights of citizens, the Constitution recognizes the protection of public health, most often as one of the reasons for restricting some of the constitutionally guaranteed rights and freedoms, such as freedom of movement, assembly, freedom of entrepreneurship, the right to work of churches and religious communities.

The laws governing health care are derived from the aforementioned constitutional norms. They are numerous, while the most important ones are: the Law on Health Insurance, the Law on Health Care, the Law on Patients' Rights, the Law on Protection of the Population from Infectious Diseases, the Law on Protection of the Population on Tobacco Exposure, the Law on Human Organ Transplantation, the Law on Prevention and Diagnostics genetic diseases, genetically conditioned anomalies and rare diseases. These laws are also the most relevant to the matter covered by Chapter 28.

Some laws deal with the systemic and organizational regulation of the health care system; some tackle the preventive role of public authorities and citizens in health protection. At the same time, some regulate situations in which the health of the population has already deteriorated. Despite the predominant orientation of specific laws, they mainly touch on the preventive aspects of health protection and those that occur when citizens' health is already damaged, so it is necessary to apply the treatment.

In the context of health protection, the Law on Patients' Rights is most often mentioned in public because it defines the concept of patients' rights, ie the rights of persons whose health is endangered or potentially endangered. This significantly affects the manner and circumstances under which the protection of an individual's health is performed. The law includes in patients' rights the right to access health care; the right to information; the right to preventive measures; the right to quality of health care provision; the right to patient safety; right to notice; the right to free choice; the right to another expert opinion; the right to privacy and confidentiality; the right to consent; the right to inspect medical records; the right to the confidentiality of data on the patient's health condition; the right of the patient in medical research; the rights of the child during hospital treatment; the patient's right to leave the inpatient health care facility at his own risk; the right to relief from suffering and pain; the right to respect the patient's time; the right to object and compensation.

2.2. Institutions for implementation and protection of fundamental rights in Chapter 28

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7 Article 68 of the RS Constitution
8 Article 74 of the RS Constitution
9 Article 90 of the RS Constitution
The key bearers of consumer protection are the line ministry, citizens' associations for consumer protection, bodies for out-of-court settlement of consumer disputes, and courts before which the procedure in consumer disputes is conducted.

**The Ministry of Trade, Tourism and Telecommunications** (hereinafter: the Ministry of Trade), among other things, creates a consumer protection policy and monitors its implementation through other state policies, prepares and submits to the Government for adoption planning acts in this area, prepares laws and regulations and improves legal framework for harmonization with EU regulations, ensures the application of regulations and coordinates market surveillance in the field of consumer protection, supports the work and development of consumer protection associations and unions, supports the establishment and coordination of the development of out-of-court consumer dispute resolution bodies and performs other tasks in the field of consumer protection following the law. The Ministry is responsible for conducting the procedure and determining measures to protect the collective interest of consumers. In the Ministry, activities in this area are performed in a special sector for consumer protection.

Citizens' associations and consumer protection associations (hereinafter: consumer organizations) represent an important segment of the institutional framework of consumer protection. Usually, they are the first and only address to which consumers can turn for advice and support to exercise or protect their rights. Consumer organizations are citizens' associations and unions registered with the Ministry of Trade under special legal conditions. By joining this Register, the consumer organization acquires certain rights and obligations, such as the right to apply for incentives from the Ministry of Trade with a program of public interest, to initiate proceedings to protect consumers' collective interest, to represent consumer interests in court and out-of-court proceedings. It is legally possible to represent consumers' interests in consultative bodies in consumer protection at the national, regional, and local levels, participate in working groups for the preparation of regulations and strategic documents governing consumer rights, etc. Currently, the records contain 26 registered consumer organizations, but this number has stagnated since 2015.11

The Law on Consumer Protection envisages special bodies' existence and works for out-of-court settlement of consumer disputes. The conduct of which the Ministry regulates in more detail the conditions, rules, and criteria for their work. Out-of-court dispute resolution bodies are entered in a special list kept by the Ministry of Trade, based on prescribed conditions and standards, and from among persons who have mediators' status, following the law governing mediation in dispute resolution, i.e., permanent arbitration institution under the law governing arbitration. The list of bodies contains eight registered bodies, but in practice, their work is not noticeable.12

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12 [https://mtt.gov.rs/download/LISTA_TEPA_ZA_VANSUDSKO%208.pdf?script=lat](https://mtt.gov.rs/download/LISTA_TEPA_ZA_VANSUDSKO%208.pdf?script=lat)
The institutional framework for consumer protection in judicial protection consists of courts that are competent for consumer disputes following the law governing courts' jurisdiction\textsuperscript{13}. In particular, in a consumer dispute, jurisdiction in the first instance belongs to the basic courts, including litigation arising from enforcement based on a credible document to settle monetary claims arising from utilities and related activities. In the second instance, in these proceedings, as a rule, the higher courts have jurisdiction\textsuperscript{14}. Besides, an administrative dispute may be initiated before the Administrative Court against the decision of the Ministry of Trade, issued in the procedure of protection of collective interest.

In addition to the mentioned institutions, the market and tourist inspection act in consumer protection, which are responsible for inspection supervision over the implementation of the prescribed rules of consumer protection and determine measures to eliminate the observed irregularities and initiate the procedure of sanctioning established violations. However, the inspection does not provide direct assistance to consumers. The subject of inspection supervision is not protecting subjective consumer rights, but the influence on the trader's behavior through administrative measures and sanctions aimed at eliminating or preventing illegal actions and business practices that violate prescribed rules in this area.

The Law on Patients' Rights provides citizens with several ways of protection. If the patient considers that he has been denied health care or any of the rights from health care, he has the right to object. Within a health care facility, a patient may file a complaint with the health care provider who manages the work process or with the director of the health care facility. Alternatively, the complaint can be addressed to the Counselor for the Protection of Patients' Rights appointed in the local self-government unit. If the patient is dissatisfied with the procedure's outcome, he can also address the Health Council, also established at the local self-government. At this level of protection, the patient can expect some of the irregularities in healthcare workers' behavior to be eliminated. The competencies and procedures conducted by the Patient Rights Adviser and the Health Council are very similar to the mediation process.

In addition to the stated protection, the patient is left with the one that enables somewhat stricter control and sanctioning of the violation of rights:

- Addressing the inspection of the Ministry of Health.
- Filing a request for initiating a misdemeanor report due to violation of the rights under the Law on Patient Protection.
- Addressing the prosecutor's office, the police, or filing a criminal complaint on their own on suspicion that one of the criminal acts against human health has been committed.


\textsuperscript{14} If the consumer dispute by its value at the same time belongs to the dispute of lesser value, which is most often the case in practice; otherwise, in the second instance, on the appeal against the judgment of the basic court in the consumer dispute, the competent appellate court decides (Article 23, paragraph 2, item 3 of the Law on Organization of Courts).
The most common crimes are failure to provide medical assistance or negligent provision of medical aid.

The patient also has access to protection in civil proceedings. He can claim compensation for the damage caused by health care realization due to the health worker's professional error, i.e., a health associate. In this case, the patient must suffer damage to his body or for a professional mistake to cause a worsening of his health condition.

When it comes to institutional protection provided by other laws that provide health protection, in addition to inspection, misdemeanor, and criminal liability, the role in health protection is performed by persons in charge of controlling the smoking ban\textsuperscript{15}, the Biomedicine Directorate\textsuperscript{16} and the Ministry of Health\textsuperscript{17}.

3. EUROPEAN COMMISSION MONITORING: THE RULE OF LAW IN CHAPTER 28

According to the European Commission's progress reports, in the period from 2016 to the last report for 2019, the assessment of Serbia's preparedness in Chapter 28 is \textit{moderately prepared}.\textsuperscript{18} Each report states some progress made in the previous year. However, the recommendations for Chapter 28 are the same throughout this period and address the need to strengthen:

- The administrative capacity of the competent authorities for consumer protection, market surveillance, and sanitary inspection;
- The general management capacity, human resources and financial sustainability of the public health insurance fund.

In consumer protection, the report states that the work of the National Council for Consumer Protection does not give visible results. It said that there is no data available on the number of consumer lawsuits resolved in court. It is assessed that better administrative capacities are needed for consumer protection bodies and inspection services in charge of this area and product safety and non-safety issues. It is also stated that the mechanisms of cooperation between line ministries and consumer associations are not adequate. The report demands addressing unfair business practices and unfair contract terms, and vulnerable consumers must be protected. The legislation of Serbia on general product safety is partially harmonized with the acquis communautaire. For example, the recently adopted Law on Articles of General Use was partially harmonized with the acquis communautaire on cosmetics. Regarding market surveillance, the report emphasizes the need to strengthen the sanitary inspection’s administrative capacity and notes progress in terms of coordination among relevant actors of the Product Safety Council. When it comes to other issues in consumer protection, it is stated that the Law on Protection of Users of Financial Services in Distance Contracting was adopted,

\textsuperscript{15} Law on Protection of the Population on Exposure to Tobacco Smoke ("Official Gazette of RS", No. 30/2010)
\textsuperscript{16} Law on Human Organ Transplantation ("Official Gazette of RS", No. 57/2018)
\textsuperscript{17} Law on Health Insurance ("Official Gazette of RS", No. 25/2019) and Law on Health Care ("Official Gazette of RS", No. 25/2019)
\textsuperscript{18} European Commission, Annual Progress Reports for 2016, 2018 and 2019
which is intended to harmonize Serbian legislation with the acquis communautaire in this area.

In public health, the report notes that health care legislation is partially in line with the EU acquis. It pointed out that the sustainability of the public health fund is in question. The national plan for human resources in the health sector has not yet been implemented. This results in a further increase in the number of doctors leaving the country. It is stated that the centralized system of electronic health records financed by the EU is still not used, as well as that the observance of health indicators has not been ensured yet. A new tobacco control strategy has not been adopted, while tobacco control legislation is partially in line with the EU acquis. However, tobacco use in public places is not in line with EU standards. Regarding blood, tissue, cells, and organs, laws on cell and tissue transplantation have been adopted, as well as on human organ transplantation, both designed to be fully in line with the EU acquis.

The screening report in Chapter 28, in part related to the assessment of compliance and capacity for implementation of the adopted legislation in the field of consumer protection, states that Serbia is making efforts to develop a consumer protection system following EU strategies and values on consumer protection the legal framework. However, the implementation of consumer rights and the implementation of consumer policies need to be improved\(^\text{19}\). It stated that the existing National Register of Consumer Complaints should become publicly available. The cooperation of line ministries and consumer organizations should be strengthened, and the same should be done with the cooperation between the consumer protection organizations themselves. The rules on out-of-court settlement of consumer disputes regarding the lower limit of the monetary value for filing a complaint should be harmonized with the acquis communautaire. In general, product safety, legal alignment is yet to come. It is assessed that efforts should be continued to ensure market surveillance, including coordination between stakeholders and market inspectors' professional training. In the area of security issues, Serbian legislation is partially in line with the acquis. Legal alignment has yet to be completed, inter alia, when it comes to consumer rights and has yet to be confirmed in the area of misleading and comparative advertising. At the time of accession, Serbia should also be able to ensure adequate enforcement and enforcement of EU rules on consumer protection cooperation regarding minimum enforcement powers and the process of authorizing competent authorities and a single liaison office.

In terms of assessments of compliance and capacity in public health, the screening report states that there are both a basic framework and infrastructure in Serbia's field of public health. However, further capacity building is necessary for administrative capacity, including training of health workers and equipment. The report deals relatively extensively with issues in both areas, such as the needs and opportunities for the establishment of e-health, the overall financial sustainability of the health sector, the existence of medical and administrative staff in primary health care centers, tobacco control in line with the EU acquis, etc.

\(^{19}\) Screening report for Chapter 28 - Consumer protection and health protection from 15.05.2016
In the area of cross-border health hazards and the control of infectious diseases, it stated that it is necessary to further harmonize national legislation with the acquis further in this area. The report says that there are certain capacities, including the possibilities of laboratory microbiology, but that the system requires modernization, primarily through a centralized information and communication system. This integrated system should integrate the various existing ones, such as the Early Warning and Rapid Alert System (EWRS) or the system for aggregating laboratory data and reports. It should connect clinical centers, secondary health care facilities, public health facilities, and private health care providers. It estimated that data analysis is the biggest problem: at the regional level, there are epidemiological data, but there is no possibility to analyze them. At the national level, there may be knowledge but no data. Human resource management and organizational empowerment are needed, but this is difficult to achieve, among other things, because a linear freeze on new employment in public administration has been implemented. It stated that the risk of increasing the number of people suffering from infectious diseases for which there are vaccines is real and that better monitoring of antimicrobial resistance is needed, development of an antimicrobial resistance action plan. Considering the problem's scope, it requires cooperation with the EU and WHO that would contribute to a general action plan on antimicrobial resistance. In the field of blood, tissues, and cells, Serbian legislation is (was) partially harmonized with the acquis, and work on this continues at a steady pace with the support of experts from EU member states.

A particular part of the report is dedicated to patients' rights in cross-border health care, where the harmonization is not completed. The report stated that fulfilling these rights calls for amending the legal regulations relating to:

1) reimbursement of health care costs incurred by Serbian citizens abroad, with particular reference to the therapies covered; compensation levels; approval procedures; rules applicable to planned and unplanned health care; patient information;

2) health care provided to citizens of EU member states, especially when it comes to access to health care; tariffs calculated; access to patient records; information provided to the patient on applied patient safety standards; differences, if any, between planned and unplanned health care therapies;

3) establishment of a national contact center that provides patients with information (on patients' rights, levels of reimbursement; authorization procedures, appeal and protection procedures, quality and safety standards, the status of health care providers);

4) recognition of medical prescriptions (e.g., by pharmacists) issued outside Serbia, including regulations on the content of medical prescriptions (what information should be on the prescription to identify the prescriber, patient, prescription product, etc.). Besides, further legal alignment is needed in medicinal products, especially concerning human medicinal products, import rules, and acceptable clinical practices and clinical trials. When it comes to veterinary medicinal products, the rules on changes to the marketing authorization (MA) and the maximum pesticide residue level (MRL). The same statements apply to cosmetic products. In the area of inequality in access to health services, the need to continue activities to improve
the health of vulnerable groups, such as the Roma, is emphasized, as discrimination continues to dominate access to health care.

The screening report dates from 2016. In the meantime, some progress has been made in the legislative field on some of the above issues in public health, such as the adoption of the Law on Medical Devices, the Law on Human Organ Transplantation. The Law on Transfusion Medicine, the Law on Biomedically Assisted Insemination, while the assessments related to consumer rights protection are equally relevant today.

According to the European Commission’s report on monitoring the situation in the area covered by Chapter 28, the emphasis is on assessing legal harmonization and primarily technical issues, such as the administrative capacity of competent authorities and their organization and coordination. These are the Chapter’s subject, while the issues of exercising consumer rights and patients’ rights are in the background.

The Action Plan for Chapter 23 - Justice and Fundamental Rights, is essential for negotiating with the European Union on Chapter 28 for at least two reasons. The first reason is more general. The backbone of the recommendations of Chapter 23, in the section on the judiciary, is the establishment of an independent prosecutor’s office and an independent judiciary. Although individual measures, not even the recommendations on justice, do not explicitly concern the protection of consumer rights and health protection, the fulfillment of recommendations is a necessary precondition for their fair and effective protection. In the field of health protection, fulfilling these assumptions is perhaps even more critical because filing a lawsuit for damages or criminal charges against a doctor or health institution is a court battle between an individual patient and an institution whose founder is usually the Republic of Serbia. If the prosecution and judiciary are more severely dependent on the executive or the legislature, it is clear that judicial protection cannot be fair.

Another reason why Chapter 23 is essential for Serbia's progress in Chapter 28 is the recommendations that explicitly require the inclusion of the health system in anti-corruption activities, protection of fundamental rights, and protection of national minorities. For example, in the field of anti-corruption, the Action Plan for Chapter 23 obliges the analysis and change of the legal framework in health care so that it has a preventive effect on eradicating conflicts of interest and corruption in health care, including strengthening inspections.\(^{20}\)

In the area of Fundamental Rights, access to health care for persons brought and detained who are at risk of torture is required and consistent application of the rulebook on physical restraint and isolation of persons with mental disorders treated in psychiatric institutions\(^{[2]}\). The action plan envisages the adoption of the Law on the Protection of Persons with Mental Disorders, enhanced supervision over living conditions in psychiatric hospitals, as well as the development of particular protocols for the protection of children from abuse and neglect, which will be applied in health care institutions.\(^{21}\)

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\(^{20}\) Recommendation 2.2.10

\(^{21}\) Recommendation 3.6.1
The recommendations aimed at improving the conditions in which Roma live, explicitly require institutions to improve access to health care services, even through the introduction of intermediaries - health mediators\textsuperscript{22}.

The last annual report of the European Commission on progress (2019)[1], in the assessment of progress in Chapter 23, in terms of health protection, states that the health system is still particularly vulnerable to corruption and that there has been no visible progress in this area. The Protector of Citizens reduced the scope of supervision over possible acts of torture, including supervision in psychiatric institutions, that torture is an accepted practice in police structures. It also stated that the prison hospital in Belgrade has been renovated, but that, more broadly, the conditions for providing health care in prison systems are still unsatisfactory. Improving the living conditions of Roma was assessed as inefficient, without a clear division of tasks between national and local authorities, which affects the unequal position and availability of health mediators, as well as the fact that only 12.7% of Roma children are vaccinated (compared to 70.5% of non-Roma).

4. CURRENT ASSESSMENTS OF THE RULE OF LAW IN CHAPTER 28

The substantive provisions of consumer law and the overall concept of consumer protection are entirely the legal harmonization results with the acquis communautaire. They are primarily aligned with it at the normative level. The degree of harmonization and remaining open issues will be considered in the coming period after opening negotiations in this Chapter. However, it can be stated that the focus of consumer protection is not on regulations but their implementation in the business practice of economic entities, i.e., traders. State bodies responsible for monitoring implementation and supervision, as well as in court practice.

According to the existing legal and institutional framework, the basic and primary instrument of consumer protection is a complaint, which requires the trader to fulfill the conformity of goods or services or to exercise another legally guaranteed right. Receiving and giving answers to this request is subject to inspection supervision, and violation of that obligation of the trader is sanctioned as a misdemeanor. In practice, however, traders generally reject a request by staying on the response in the form of a "rejection", a generic answer for no reason directly related to the complaint or request from the complaint. The leading cause of this phenomenon is the lack of an effective consumer protection mechanism in individual situations. Consumer warnings that they will exercise their right in court, as a rule, do not affect the trader because traders are aware of the difficulties consumers face when accessing justice in such matters, relatively high potential costs of proceedings for the consumer as a prosecutor, problems in the evidence faced by the consumer, and general possibilities for legal unpredictability and lengthy court proceedings.

In case of rejection of the trader's request or complaint, the next step available to consumers is to file a consumer complaint, like a petition or complaint reporting a violation of consumer

\textsuperscript{22} Preporuka 3.8.2
rights. The consumer complaint cannot be qualified as an instrument of legal protection because it does not initiate any procedure. It does not imply sanctioning non-compliance with the request contained in it. However, it represents a request for help submitted or sent to consumer organizations, directly or through the Ministry of Trade website. It is up to them to give advice, legal support, or solve the problem through informal mediation with the trader. We need to have in mind that the consumers have limited resources and no legal protection instruments for this.

The last step, available to consumers before filing a lawsuit against the trader, is a request for out-of-court settlement of disputes. The Law on Consumer Protection envisages mediation and arbitration as forms of out-of-court dispute resolution, prescribed conditions for registration and work of special bodies, and the existing mediation model is based on the valid legal framework governing mediation in dispute resolution. However, to date, a relatively small number of intermediaries have been entered in the list of bodies for out-of-court settlement of consumer disputes. No official data on the number of cases resolved in this way are available. According to earlier estimates, there are only a few consumer disputes in the procedure before the body for out-of-court settlement of these disputes on an annual level. Besides, no functional consumer arbitration has been established so far.

Judicial practice in consumer disputes is insufficient, sporadic, and does not ensure the possibility and certainty of protecting individual rights and interests. At this moment, it is not possible to speak with confidence about the case law in this matter based on court statistics because the procedure on consumer lawsuits is not specifically systematized in the register. It is conducted under the general "P" mark, which significantly complicates analytical processing in court statistics. However, the Law on Civil Procedure recognizes this procedure as special and contains specific special procedural rules. Cases considered as consumer disputes according to the criteria of the Law on Consumer Protection, in practice, are usually the result of legal support provided by consumer organizations, which provide legal assistance, and sometimes appropriate representation through attorneys with whom they cooperate, in cases where the consumer files a lawsuit.

A special issue is the qualification of court cases that arise from consumer relations when the consumer gets sued. This primarily refers to litigations that are a consequence of the enforcement debtor's objection filed against the enforcement decision based on a credible document to settle a monetary claim arising from utility services and related activities. The most common complaint heard from representatives of consumer organizations who provide legal support to consumers in court cases is that the court rarely and reluctantly accepts the Law on Consumer Protection's validity. It is not uncommon to face incorrect application of its rules or bylaws. Often there is not even a sufficient level of knowledge of consumer law. A particular problem is the rules on a proof. The legally prescribed burden of proving the trader in the matter of lack of conformity of goods or services is often ignored within the legal

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23 Law on Mediation in Dispute Resolution ("Official Gazette of RS", No. 55/2014)
24 Chapter XXXV "Procedure in Consumer Disputes", Art. 488 to 493 of the Code of Civil Procedure
deadline of his liability for non-conformity. Besides, access to court in consumer matters is further hampered. Consumer cases are of relatively low value. The costs of proceedings can be many times higher than the value of the dispute's subject matter, especially the costs of representation and expertise. In a consumer dispute whose value does not exceed the amount of 500,000 dinars, the plaintiff should be exempted from the court fee, but this rule is not applied consistently in practice.

**Access to court** in consumer matters is characterized by obstacles, reflected in legal unpredictability, length of proceedings, uncertainty regarding the application of applicable law, and the possible amount of total costs concerning the dispute's value, which significantly deter consumers from initiating court proceedings. On the other hand, to improve judicial protection, it is necessary to form and unify applying consumer law. Hence, a vicious circle appears, in which there are not enough consumer lawsuits due to these obstacles and fair court practice due to insufficient case influx.

**Access to adequate legal aid** is one of the biggest problems in consumer protection, bearing in mind that the consumer mostly has no economic interest in hiring a lawyer in a case of relatively low value. Especially considering the possible costs of hiring lawyers, regardless of the merits of the claim and (uncertainty) success dispute. Although in practice, lawyers often assist at a minimum rate or pro bono, the only real address for legal assistance and support is one of the consumer organizations. According to the existing program of regional consumer counseling centers, each of the seven counseling centers in the four regional centers has at least one engaged lawyer who provides legal assistance or support to consumers who apply to such applications.25 On the other hand, the Law on Civil Procedure does not allow the attorney of the party who has the status of a consumer in a consumer dispute to represent a registered consumer organization, who meets the appropriate professional qualifications.26 We should have in mind the restrictive legal regime of the recently adopted Law on Free Legal Aid27 when talking about access to justice, protecting consumer rights, and providing legal aid by consumer organizations following the powers of the Law on Consumer Protection.

As consumer disputes are, as a rule, of relatively small value, court proceedings that involve a significant expenditure of time and resources, as well as uncertainty regarding the proper application of consumer law, are certainly not ideal for resolving them. Out-of-court settlement of consumer disputes appears as the most reliable way to resolve disputes quickly and efficiently, in a competent manner, and with the lowest possible costs. Ahead, there was more talk about the shortcomings of out-of-court dispute resolution in practice. Representatives of consumer organizations point out that this phenomenon's leading cause

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25 The program of regional consumer counseling centers of the Ministry of Trade, Tourism and Telecommunications, which finances the work of four regional consumer counseling centers every year, and on the basis of which seven consumer organizations that run these counseling centers were supported in 2019

26 On the contrary, the possibility is prescribed that the attorney of an employee in an employment dispute may also be a representative of the trade union of which he is an employed member, provided that he is a law graduate with a bar exam (Article 85, paragraph 3 of the LCP).

27 Law on Free Legal Aid (“Official Gazette of RS”, No. 87/2018)
is the lack of traders' motivation to participate in mediation or any other form of out-of-court dispute resolution. Traders are aware that access to justice in consumer matters is difficult and uncertain. Apart from inspections and misdemeanor penalties, there is no effective mechanism to ensure compliance with prescribed rules. Also, there is often no intense competitive pressure in the market, and that consumers are left to the goodwill of traders. At the same time, there is not enough pressure on possible reputational damage for traders due to their failure to comply with justified consumer demands, leading them to believe that there is no need to engage in a substantive examination of consumer demands and solve their problems. Therefore, defining and affirming a useful model of out-of-court settlement of consumer disputes appears as one of the priorities in the field of consumer protection.

When it comes to health protection, including protecting patients’ rights, the most relevant domestic assessments include primarily assessments of the situation published by an independent state body - the Protector of Citizens. He protects citizens’ rights and controls the work of bodies, organizations, companies, and institutions entrusted with public authority.

In the Regular Annual Report for 2019\textsuperscript{28}, the Ombudsman, in the section dedicated to health protection, especially pointed out that:

- the Ministry of Health should take measures within its competence to improve the application of the measure of physical restraint by tying patients in psychiatric hospitals;
- During 2019, citizens pointed out the difficulties in exercising the rights from the compulsory health insurance, primarily in connection with scheduling specialist-consultative examinations;
- During 2019, citizens pointed out the alleged professional errors in treating patients and the generally lower level of quality of health services provided.

In the Special Report of the Protector of Citizens on the work of mechanisms for the protection of patients’ rights\textsuperscript{[1]}, published in 2016, the Protector states that he found that the system of newly established mechanisms for the protection of patients’ rights did not come to life in practice. Competencies in the manner and within the period prescribed by the Law on Patients’ Rights. This created omissions that can aggravate patients' legal position and have the consequence of violating rights and creating legal uncertainty.

4.1. Example of the Rule of Law in the Chapter

During the state of emergency and the declared epidemic of special epidemiological significance, caused by the coronavirus, it was established that one health institution made publicly available the username and password for access to the Information System COVID-28

\textsuperscript{28} \url{https://www.ombudsman.rs/attachments/article/6542/Redovan%20godišnji%20izveštaj%20zaštitnika%20gdana%20za%202019.%20godinu.pdf}
According to the Government decision on setting-up the Covid 19[2] information system, health institutions had to update the program with the data on people who were cured, deceased and tested (whether positive or negative), who are being treated, who were sentenced to self-isolation or accommodation in temporary hospitals, with information on their location. The system also contains data on possible carriers of the virus due to contact with patients. Healthcare institutions updated this data daily.

Data from the Information System Covid-19 of one of the health institutions were publicly available for eight days during April 2020, within this institution's internet presentation. This would fundamentally violate the right to privacy and confidentiality of patient data. Still, it is particularly worrying that such an omission occurred during an epidemic of the highly contagious virus when any data from the Information System can significantly affect patients, their families, and people with whom they were in contact.

5. RECOMMENDATIONS
The critical issues in negotiating Chapter 28 are the exercise of consumer rights and health protection and the impossibility of access to justice for their protection. These will be considered in the continuation of the negotiation process after the opening of negotiations in this Chapter. Realization and protection of consumer rights, protection of patients' rights, and free access to information of public importance are points of intersection with the improvement of the situation in the field of justice and fundamental rights, the subject of the negotiating Chapter 23. As possibilities for solving this complex and multilayered issue, the following recommendations are given for improving the existing legal and institutional framework in the field of consumer protection and health protection:

5.1. Protector of consumer rights
The answer to the lack of an institutional structure that would provide a simple, efficient, and economical procedure for resolving consumer complaints could be provided by the Protector of Consumer Rights, as a form of the specialized ombudsman. The Protector of Consumer Rights would be an institution modeled on other ombudsman-type institutions, the Protector of Citizens, the Commissioner for Information of Public Importance and Personal Data Protection, and the Commissioner for the Protection of Equality, who raised public awareness of the importance of citizens' subjective rights and have achieved significant and relevant practices for the protection of these rights, the work of which is the subject of Negotiating Chapter 23.

The Protector of Consumer Rights would be an independent state body, which would investigate consumer rights violations in proceedings initiated by a consumer complaint. This is a critical phase for consumers after receiving a "rejection" on the complaint. Before any further action before the court, it is necessary to provide an efficient, informal procedure, which opens the possibility of dealing with mass cases of injuries of the ombudsman institution. Besides, the procedure could be initiated ex officio in matters of protection of consumers' collective interest. The supervision procedure could end with a recommendation.

https://www.sharefoundation.info/sr/pandemija-jedne-lozinke/
to the supervised entity. The trader sanctioned appropriately with an in case of non-compliance with the recommendation and the possibility of public disclosure of the list of traders who do not comply with the recommendations, bearing in mind that reputational damage. The Protector of Consumer Rights, in addition to the above supervisory function, would take on the role of a critical national institution in this area, a position currently vacant, as he could become a significant advocate of consumer policy in public and a holder of proposals and measures to improve the situation.

5.2. Out-of-court settlement of consumer disputes - Consumer arbitration
Protecting the rights through the court in consumer matters, as a rule, implies a procedure whose costs are significantly higher than the value of the dispute, a procedure that requires adequate legal representation through a lawyer and thus causes additional charges and a relatively long duration. Out-of-court settlement of consumer disputes appears as the most reliable way of quick and successful dispute resolution, which has not yet found appropriate application in practice. It is necessary to create a model of out-of-court settlement of consumer disputes, which provides an efficient and economical procedure and independence and competence in applying the law. Consumer arbitration represents such a possibility because it ensures simplicity and efficiency in the procedure. At the same time, the contradiction of the procedure in which the dispute is discussed is preserved. The decision made at arbitration is binding for both parties to the dispute and affects an executive document. Simultaneously, the introduction of alternative dispute resolution methods is one of the activities envisaged in the Action Plan for Chapter 23 in part related to the judiciary.

The preconditions for the establishment of Consumer Arbitration are, above all, of an organizational nature. They are also related to the possibility of contracting an arbitration clause. Permanent consumer arbitration could be established on the Serbian Chamber of Commerce's organizational platform, as its independent body, independent in work and decision-making, and with a special list of specialized arbitrators. Creating and establishing this model is also in the interest of retailers because the successful and timely resolution of consumer disputes fits into the business policy of retaining regular customers and service users and building the business reputation of a socially responsible company. Raising awareness of the importance of strengthening consumer confidence and fair trade practices for their business are some of the elements for increasing traders' readiness to resolve consumer disputes in this way, thus creating another assumption, negotiating an arbitration clause in concluding consumer contracts.

5.3 Out-of-court settlement of consumer disputes - Consumer arbitration
According to the previously presented assessments of domestic and international institutions, it is necessary to ensure the functional protection of patients' rights through consistent application of the law - especially when patients turn to a health institution and competent bodies of local self-government units for protection. Health institutions, local self-
government units, and the Ministry of Health must take steps to enable the legally prescribed protection procedure to give visible results, which is not the case. It is also necessary for patients to have clear and publicly available information on possible protection methods and gain trust in them, including trust in the judicial protection of rights.

Relevant institutions, such as the Inspectorate and the Protector of Citizens, must pay particular attention to the situation of patients in psychiatric hospitals and the treatment of other particularly vulnerable groups of patients, such as Roma or those detained or deprived of their liberty.

5.4. Improved public reaction in regulating the field of health care

Bearing in mind that Chapter 28 covers health protection, a term broader than the protection of patients' rights, it should be pointed out that regulations governing health protection, whether related to tobacco smoke protection, organ transplantation, biomedically assisted fertilization or any other area, are adopted without inclusive public hearings, often by urgent procedure. Adopted changes or new solutions are usually not the subject of public information, including mechanisms for the protection of citizens in the application of numerous laws on health protection. This creates the impression that the regulations on health protection are exclusively of a professional-medical nature, that citizens should therefore not have an influence on their adoption, and that information about these regulations should occur only when citizens become subjects of some of these regulations. This approach needs to change without delay and involve citizens in discussions about ways to protect health. It is especially necessary to open public space, and in particular, the space of public media services, to provide information on legal solutions in the field of health protection, and especially those concerning the possible protection of citizens' rights.