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Doc. Jelena Arsić, LL.D.*

Assistant Professor,
Law School, Union University, Belgrade

Prof. Jelena Jerinić, LL.D.*

Associate Professor,
Law School, Union University, Belgrade

Doc. Jelena Simić, LL.D.*

Assistant Professor,
Law School, Union University, Belgrade

COMPULSORY OR RECOMMENDED VACCINATION: LEGAL ASPECTS OF CHILDREN VACCINATION POLICIES IN SERBIA

Abstract: *Vaccination is one of the most important tools of primary health prevention. However, vaccines are specific and differ from other medical interventions, mainly because they are one of the most common medical measures applied to healthy rather than ill persons. They are aimed not only at ensuring the wellbeing of the individual who receives them but they are also indirectly beneficial for the entire population. This paper examines the issues pertaining to the vaccination of children in light of the Serbian Act on the Protection of Population from Infectious Diseases, adopted in 2016. The authors consider relevant legal aspects of childhood vaccination, and analyse the potential conflict between children's right to protection from diseases and the parents' or legal guardians' right to make a decision regarding the treatment of children. International policies and standards are also explored, with the aim to reach conclusions on the appropriate legal measures to balance the necessity to provide for the protection of public health with the individuals' right to self-determination and freedom of choice.*

Key words: *children, vaccination, public health, right to healthcare, right to self-determination.*

* jelena.arsic@pravnofakultet.rs

** jelena.jerinic@pravnofakultet.rs

*** jelena.simic@pravnofakultet.rs

1. Introduction

Vaccination is one of the most important tools of primary health prevention. In the past 50 years, vaccination saved more lives worldwide than any other medical product or procedure.¹ Yet, despite a long history of effectiveness, vaccines have always had their critics. Some parents, as well as some doctors, question whether vaccinating children is worth what they perceive as risks. The situation is similar in Serbia. Even though compulsory immunization of children in Serbia was initially prescribed decades ago, it was only the adoption of the Patients' Rights Act² in 2013 that brought about a change in citizens' attitudes, as they increasingly began to reject compulsory vaccination of children.³

The number of vaccines, both compulsory and recommended, in immunization calendars has grown over the years; but, does this make us healthier? There have been severe disputes lately over this question, and the topic of justifiability of vaccination has been frequently discussed. Ever since the first vaccine against smallpox was discovered in 1796, vaccination has been followed by controversy⁴, and the dispute regarding vaccination of children persists to this day, more than two centuries later. People question whether vaccines do children more harm than good. Are vaccinations dangerous or superfluous? What is the role of the

1 According to the UK Health Protection Agency (HPA), apart from clean water, vaccination is the second-most effective public health intervention worldwide, saving lives and promoting good health (Fine-Goulden, 2010: 1).

2 Zakon o pravima pacijenata (the Patients' Rights Act), *Sl. glasnik RS*, 45/13.

3 81% of children in the general population received all vaccinations recommended in the national immunization calendar by their third birthday, while this is the case for fewer than half of children in Roma settlements (44%). However, only 66% of children in the general population were fully immunized within the prescribed timeframe (*Full vaccination includes the following: BCG, Polio3, DPT3, HepB3, Hib3 by 2 months of age and Measles (MMR1) by 24 months of age*) See UNICEF Multiple Indicator Cluster Survey 2014 (MICS 5), Retrieved 24, May 2017, from <https://www.unicef.org/serbia/MICS5-English-KeyFindings-10Jul2014.pdf>, See also Annual report on immunization in the Republic of Serbia for the year 2016, 2015 and 2014. (Institut za javno zdravlje, dr Milan Jovanovic Batut, 2017: 3; Institut za javno zdravlje, dr Milan Jovanovic Batut, 2016: 3,4); Institut za javno zdravlje, dr Milan Jovanovic Batut, 2015: 3).

4 For example, when mandatory smallpox vaccinations were introduced by the "Reichsimpfgesetz" (German Imperial Vaccination Act) of 1874, the debate was fierce. Vaccine critics even started a journal "The Vaccination Objector" (*Der Impfgegner*) in order to create a platform for their arguments, opposing such a legal act (Robert Koch-Institute, 2016). A similar issue arose in Great Britain after the 1853 Vaccination Act, introducing compulsory vaccination for 3-month-olds, and Vaccination Act of 1867 which prescribed that every child aged 14 or less has to undergo vaccination, while anyone rejecting vaccination would be sanctioned. This led to the formation of the Anti-Vaccination League and publication of the first anti-vaccination journals (Wolfe, Sharp, 2002).

pharmaceutical industry and its profit motive? One thing is clear: vaccinations are different from other medical interventions as, *inter alia*, they are given to healthy subjects; they do not aim to provide benefit only to the individual who receives it but indirectly to the entire population. Therefore, it is quite justified to demand special care when it comes to vaccinations, and to discuss controversial issues critically, primarily for the reason that vaccines are one of the most common medical procedures of all.

This paper will cover various medical, administrative, and family law aspects related to compulsory vaccination of children in Serbia, including legal dilemmas supported by the new Act on the Protection of Population from Infectious Diseases of 2016⁵. In terms of medical law issues, we will analyze the existing rules on vaccination in the context of right to self-determination and the importance of information given to the patient before vaccination. Among different administrative law aspects of child vaccination, we will discuss the role of the Sanitary Inspection, and particularly deviations from the general regime of administrative procedure in case of rulings of the Inspection. Finally, inspired by several announcements of the line ministry officials, we will look at the real legal risks facing parents who oppose vaccination to be deprived of their parental rights, as a consequence of choosing not to have their children vaccinated.

2. About Compulsory Vaccination

Immunization is a process whereby a person is made immune or resistant to an infectious disease, typically by the administration of a vaccine.⁶ Vaccines stimulate the body's own immune system to protect the person against subsequent infection or disease. Immunization is conducted by means of immunologic agents, and it can be compulsory or recommended.⁷

In the Republic of Serbia, protection of population from infectious diseases is generally regulated by the Healthcare Act⁸ and the 2016 PPID Act covering this

5 Zakon o zaštiti stanovništva od zaraznih bolesti (the Act on the Protection of Population from Infectious Diseases), *Sl. glasnik RS*, 15/16, hereinafter: 2016 PPID Act.

6 Immunization is a preventive measure of protection of people from infectious diseases by administering vaccines and/or immunoglobulins of human origin, immunobiological products containing specific antibodies, or monoclonal antibodies. *See* Art. 2, para. 1, item 21 of the 2016 Act.

7 Recommended immunization is the immunization recommended by a medical doctor or a specialist of the given medical field, in line with the program of population immunization against certain infectious diseases. *See* Art. 32, para. 5 of the 2016 Act.

8 Zakon o zdravstvenoj zaštiti (the Healthcare Act), *Sl. glasnik RS*, 107/05, 72/09, 88/10, 99/10, 57/11, 119/12, 45/13, 93/14, 96/15, 106/15; The Healthcare Act prescribes compulsory immunization provided in line with the provisions of the 2016 PPID Act.

topic in depth, accompanied by appropriate bylaws.⁹ Compulsory immunization is the immunization of a person of a certain age, as well as other persons as prescribed by law, which cannot be refused by the person receiving immunization or the parent or guardian, unless there is a medical contraindication which is determined by a specialized medical doctor, or an expert team for contraindications.¹⁰ Compulsory immunization of a person of a certain age refers to immunization of children, according to a certain schedule and at an age when they are most sensitive and when contracting an infectious disease may carry the highest risk of complications. Since post-vaccination protection reduces with time, certain doses of vaccines are given again to "remind" the immune system and reinforce the defense of the organism.

Immunization calendars differ from one country to another, conditioned by the varieties related to current epidemiological situation, social-economic development, organization of healthcare services and cultural setting (Lončarević, Kanazir, 2011: 4). Compulsory systematic immunization aims at achieving and maintaining 95% or higher coverage of the compulsory immunization program on the level of the entire population of children to be vaccinated according to the immunization calendar (including all children, with all vaccines, without any demographic, territorial or social differences), in order to prevent contraction of diseases, as well as potential complications requiring hospitalization, some of which leave permanent damage and death outcomes (Lončarević, Kanazir, 2011: 4).

In the EU, organization of vaccination programmes differs considerably between countries. Differences relate to the vaccines included in the programme, the type of vaccines used, the total number of doses administered, the timing

9 See Uredba o programu zdravstvene zaštite stanovništva od zaraznih bolesti, *Sl. glasnik RS*, 22/16; The 2016 PPID Act envisaged a wide range of issues subject to secondary regulation by the Ministry of Health and in respect of immunization and compulsory vaccination two rulebooks to be passed until March 2017 (see Art. 7 para. 9, 39 para. 3 and 87). One was adopted in January 2017 (Pravilnik o vrstama i načinu sprovođenja epidemiološkog nadzora nad zaraznim bolestima i posebnim zdravstvenim pitanjima, *Sl. glasnik RS*, 3/17) while in the case of the other, an old rulebook still applies (Pravilnik o imunizaciji i načinu zaštite lekovima, *Sl. glasnik RS*, 11/06, 25/13, 63/13, 99/13, 118/13, 65/14, 32/15).

10 Immunization is compulsory for persons of a certain age (against tuberculosis, diphtheria, lockjaw, whooping cough, polio, smallpox, rubella, mumps, hepatitis B virus, diseases caused by haemophilus influenza type B, and diseases caused by streptococcus pneumoniae), but also for persons exposed to certain infectious diseases, persons employed in healthcare institutions against certain infectious diseases, persons at particular risk of specified diseases, and international travelers, as per the requirements of the destination country. See Art. 32 of the 2016 Act.

of vaccinations, etc. (Haverkate, D'Ancona, Giambi, Johansen, Lopalco, Cozza, Appelgren, 2012: 5).

There are also large differences in whether vaccinations included in the national programmes are recommended or mandatory. Mandatory vaccination can be enforced by legislation, even though the term 'mandatory' has to be interpreted differently in individual countries (Haverkate et al., 2012: 2). Mandatory vaccination is a vaccination that every child must receive as prescribed by law without the possibility for the parent to choose to accept the uptake or not, regardless of legal or economical implications of the refusal. Recommended vaccination is a vaccination included in the national immunisation programme for all or for specific groups, state funded or not, implying "vaccine included in the national immunisation plan but not mandatory" (Haverkate et.al., 2012: 2).

By analyzing how European countries regulate the matter of childhood vaccination, one may notice two approaches.¹¹ There are countries, including Serbia, which prescribe compulsory childhood vaccination (Hungary, Slovenia, Slovakia, Poland, Macedonia, Croatia, Italy, etc.).¹² In these countries, the number of compulsory childhood vaccines varies from 11 (Serbia), four (Italy), to two (France).¹³ The second group comprises countries that do not prescribe childhood vaccination by law, but rather cherish the policy of "recommended vaccines" (Austria, Great Britain, Denmark, Estonia, Lithuania, Luxembourg, Germany, Norway, Finland and Sweden).

Legal consequences of non-vaccination differ across national legal systems; they may include quite severe pecuniary penalties, conditioning of attending public schools, or even penal consequences for parents, as well as milder ones, including the possibility of choosing to 'opt-out' (Haverkate, *et al.*, 2012: 2). Moreover, enforcement varies in practice. In some countries, the envisaged penalties may never be applied.

11 A total of 15 EU countries do not have any mandatory vaccinations; 14 EU countries have at least one mandatory vaccination included in their programme. Vaccination against polio is mandatory for all children in 12 EU countries; diphtheria and tetanus vaccination is mandatory in 11 EU countries, and hepatitis B vaccination is mandatory in 10 countries. For eight of the 15 vaccines considered here, some countries have a mixed strategy of recommended and mandatory vaccinations. Usually this means that the vaccination is recommended for the whole population, but that it is mandatory for some risk groups. This data has been taken from the Vaccine European New Integrated Collaboration Effort (VENICE) network. The information was collected from all 27 EU Member States, Iceland and Norway (Haverkate et al., 2012: 2).

12 For more about vaccination by country, see: the European Forum for Vaccine Vigilance website at <https://www.efvv.eu>

13 *Ibid.*

3. Key Features of the National Legal Framework

In respect of compulsory vaccination of children, the 2016 PPID Act sets a system similar to the previous 2004 PPID Act, and to a large extent to the ones before it, passed during the former Yugoslavia (hereinafter: SFRY) from the 1970s to the 2000s. As previously stated, under the 2016 PPID Act, compulsory immunisation cannot be rejected, except in cases of temporary or permanent medical contraindication determined by a physician of appropriate specialisation or an expert team for contraindications (Art. 32 para. 2).¹⁴ For children, as "persons of a certain age", vaccination is compulsory against 11 diseases (Art. 32 para. 3).

Earlier legislation also envisaged compulsory vaccination of children but it covered a smaller number of diseases (ten, according to the Act on the Protection of Population from Infectious Diseases of 2004,¹⁵ or eight or six according to the earlier legislation).¹⁶ Hence, there is a constant rise in the number of compulsory vaccines and our country is among those with the highest number of compulsory vaccines for children.

The 2004 PPID Act explicitly envisaged that, in case of compulsory vaccination (of both children and other target groups), a written consent of the vaccinated person was not necessary, nor of the child's legal guardian or of a person deprived of legal capacity (Art. 25 para. 5), which is a solution that, in its practical consequences, corresponds to the present one. A novelty of the 2016 PPID Act relates to designating compulsory vaccination as a condition for enrolment and

14 The expert team is established according to the Rulebook on immunization and method of protection by drugs (Pravilnik o imunizaciji i načinu zaštite lekovima, *Sl. glasnik RS*, 11/06, 25/13, 63/13, 99/13, 118/13, 65/14, 32/15) – Art. 10.

15 *Zakon o zaštiti stanovništva od zaraznih bolesti*, *Sl. glasnik RS*, 125/04, 36/15, hereinafter: the 2004 PPID Act.

16 Before 2004, these issues were regulated by federal laws of the SFRY and, later on, by the laws of the Federal Republic of Yugoslavia, as well as by the legislation of the federal units (Serbia among them). Federal laws from the beginning of 1970s envisaged compulsory vaccination against six contagious diseases (tuberculosis, diphtheria, tetanus, large cough, childhood paralysis and smallpox – Art. 21 para. 2 of the Act on Protection of Population from Contagious Diseases endangering the whole country (*Zakon o zaštiti stanovništva od zaraznih bolesti koje ugrožavaju celu zemlju*, *Sl. list SFRJ*, 58/78), while the later republic legislation added mumps to the list. *See* Art. 26 para. 1 of the Act on Protection of Population from Contagious Diseases (*Zakon o zaštiti stanovništva od zaraznih bolesti*, *Sl. glasnik SRS*, 58/89, *Sl. glasnik RS*, 44/91, 53/93, 67/93, 48/94). In the mid-1990s, the legislation envisaged compulsory vaccination against eight diseases (tuberculosis, diphtheria, tetanus, large cough, childhood paralysis, smallpox, reddening and mumps – Art. 21 para. 2 of the Act on Protection of Population from Contagious Diseases endangering the whole country (*Zakon o zaštiti stanovništva od zaraznih bolesti koje ugrožavaju celu zemlju*, *Sl. glasnik SRJ*, 46/96, 12/98, 37/02).

attendance of preschool and primary school or institutions for accommodation of children without parental care, except in cases of contraindications (Art. 32 para. 4 of the Act).

In terms of relevant administrative law issues, the 2016 PPID Act applies a traditional method of regulating its professional and inspection oversight. Professional oversight is exercised by competent institutes for public health (Art. 37 para. 2), while inspection oversight lies in the hands of the Ministry of Health, i.e. the Sanitary Inspection (Art. 73-76).

Competences of sanitary inspectors have been regulated in the same or similar manner as in earlier legislation. In respect of compulsory vaccination of children, these include: the right and the duty to order the implementation of all measures prescribed by the Act, including compulsory vaccination (Art. 73 para. 2 item 1), to prohibit further distribution of a vaccine or an immunobiological preparation in case of non-adherence of the cold chain principle (item 9), to initiate a criminal or misdemeanour procedure in relevant cases (item 14), or to inform other competent bodies of the reasons for undertaking measures in their own competence (item 15). Considering the last item, it should be noted that the Act does not envisage, even *exempli causa*, which other competent bodies or measures within their competences this applies to. In relation to these issues, there are no relevant bylaws, such as instructions or similar. Several statements issued by the Ministry of Health officials in the previous years, warning parents who oppose vaccination that they could be deprived of their parental rights (although without a clear legal ground for such an action), represent only one of the problems. Therefore, the Act leaves an enormous gap allowing for various interpretations, thereby supporting legal insecurity.

When mandating a measure, the inspection does so by an individual administrative act – a written ruling (Art. 75), passed in accordance with the General Administrative Procedure Act¹⁷. In case of extremely urgent matters, necessary to overcome an immediate threat to life and health of the people, these measures can be mandated by an oral ruling (Art. 75 para. 2), which naturally will not be the case when it comes to compulsory vaccination of children.

The first instance ruling can be appealed before the Minister of Health, within eight days, and the appeal does not suspend its execution. By this, the Act sets exceptions from the general regime of administrative procedure, envisaging a general 15-day appeal deadline and the suspensive effect of administrative appeal, as a rule.¹⁸ The final decision of the Minister can be appealed before the

17 Zakon o opštem upravnom postupku, *Sl. glasnik RS*, 18/16, hereinafter: „GAP Act“.

18 See Art. 153 and 154 GAP Act and Art. 39 of the Act on Inspection Oversight (Zakon o inspekcijskom nadzoru, *Sl. glasnik RS*, 36/15).

Administrative Court, in the procedure of administrative dispute, according to general legislation.¹⁹

As all laws before it, the 2016 PPID Act contains penal provisions, within which it envisages misdemeanour pecuniary sanctions for different offenders, including health institutions, physicians, legal entities and persons (Art. 77-85). In terms of compulsory vaccination of children, particularly relevant provisions include those on penalties in case of: non-application of measures prescribed by law in general and by a decision of the sanitary inspector (Art. 75 para. 1 item 9 and para. 5); omission of a health institution to organise and implement immunization in accordance with the law (Art. 79 para. 1), or of a public health institute to oversee immunization in accordance with the law (Art. 80 para. 1 item 3); a physician who does not implement immunization or does not keep the prescribed records of immunization (Art. 84 para. 1 item 3); or a person who rejects compulsory immunization (Art. 85 para. 1 item 6).²⁰

Misdemeanour penalties for persons (in this case, parents) range between 20.000 and 50.000 Serbian Dinars. However, most applications submitted by sanitary inspectors to the Misdemeanour Courts, based on information from primary healthcare centres, have ended with warnings instead of pecuniary penalties. Healthcare institutions could be penalised if they do not report on these cases and do not implement the prescribed measures by imposing a penalty of 100.000 to 800.0000 Serbian Dinars.

Media reported that in 2016 misdemeanour courts received over a thousand initiatives based on violations of the PPID Act, including cases of rejection to vaccinate children (although their exact number is not publicly available). According to data issued by the Ministry of Health, 40 percent of these cases have been decided in courts. Most cases came from larger urban areas, such as Kragujevac, Subotica, Novi Sad, Belgrade, Nis and Zrenjanin.²¹ Similar statistics have been reported in 2017, even though some courts have issued first pecuniary fines.²²

19 The Administrative Disputes Act (*Zakon o upravnim sporovima, Sl. glasnik RS, 111/09*).

20 Related to earlier legislation, the 1989 Act envisaged that a parent or legal guardian of a minor would be penalised for certain activities, including rejection of immunization, if that was a consequence of an omission to ensure proper care for the minor (Art. 49 para. 2). Thus, not every rejection of vaccination would be penalised, unless all relevant circumstances could be considered to meet the requirements for an omission to provide proper care, in accordance with the relevant family law regulations.

21 Politika online, „Umesto kazne za nevakcinisanje dece samo opomena“, Retrieved 7. February 2017, from <http://www.politika.rs/scc/clanak/318433/Umesto-kazne-za-nevakcinisanje-dece-samo-opomene>

22 In August 2017, Belgrade Misdemeanour Court had 209 pending cases concerning children vaccination. During the first half of 2017, this court passed 32 judgements, out of which there

4. Consequences of Non-Compliance with Compulsory Vaccination of Children

4.1. Medical Law Aspects

Even though relevant Serbian laws have supported compulsory childhood immunization for decades, it was only the Patients' Rights Act of 2013 that changed the patients' attitudes and resulted in an increase in refusal of compulsory vaccination (Sjeničić, Miljuš, Milenković, 2016: 326). When refusing to vaccinate their child, parents would often refer to Article 15 of the Patients' Rights Act, which guarantees the right to consent as one of the patient's fundamental rights. The patient is, therefore, entitled to make free decisions about anything concerning his or her life and health, except when this poses a direct threat to the life and health of other persons. This also assured that no medical measure could be conducted on a patient without his or her consent, apart from the exceptional cases prescribed by law and in line with medical ethics.

As the drop in compulsory vaccination coverage started to increase, the Serbian legislator envisaged additional tightening of the measures related to the compulsory character of immunization, prescribing that compulsory immunization is the immunization of a person of a certain age, as well as other persons as prescribed by law, which cannot be refused by the person receiving immunization or the parent or guardian, unless there is a medical contraindication which is determined by a specialized medical doctor, or an expert team for contraindications.²³ However, sadly for the legislator, the expected effect – a greater coverage of vaccinated children – did not actualize, and the very tightening of the measures reopened the question of patients' right to consent to a medical intervention and the right to self-determination.²⁴ As previously mentioned, the medical law regulations instruct that no medical measure can be conducted without the consent of a person such measure applies to. The right to self-deter-

were 21 convictions: 18 warnings and three pecuniary fines. B92 online, "U postupku 209 predmeta zbog nevakcinisanja dece", Retrieved 13, August 2017, from http://www.b92.net/info/vesti/index.php?yyyy=2017&mm=08&dd=13&nav_category=16&nav_id=1292631

23 Art. 32, para. 2 of the 2016 PPID Act.

24 *See*: Results of compulsory immunizations 2013-2015 made by Statistical Office of the Republic of Serbia (Republički zavod za statistiku, 2016: 85). According to the Institute of Public Health, the main reasons for the drop in the compulsory vaccination coverage are: frequent interruptions in the distribution of vaccines (distribution of vaccines often did not go in line with the distribution plan); refusal of immunization assisted by the action of antiviralists, but also insufficiently strong attitudes and arguments related to the work of pediatricians in primary health care. (Institut za javno zdravlje, dr Milan Jovanovic Batut, 2017: 47).

mination, which is the foundation of the requirement of the patient's informed consent, may be limited in exceptional cases in order to protect the very interests of a patient, or the interests of the society as a whole. Thus, the law does not require a patient's consent in case of an emergency and necessary expansion of a medical treatment, nor in certain cases where the law requires an individual to undergo a medical intervention regardless of their potentially contrasting will. Such cases of so-called forced treatment are explicitly prescribed by the law and involve, *inter alia*, the forced treatment of suspects or prisoners, alcoholics or drug addicts, treatment of persons with mental disorders in certain cases, treatment of pregnant women, as well as compulsory immunization. However, these situations, restricting the patient's right to self-determination, should be observed as mere exceptions from the basic principle of medical law "*salus et voluntas aegroti suprema lex est.*"²⁵

On a regular basis, before performing the vaccination, a physician has the duty to provide all relevant information to the person about to be vaccinated; in case of persons under 15 years of age, the information shall be given to a parent or a person who is entrusted with child care and education so that they can make fully-informed decision on whether to participate in the vaccination.²⁶ The information given before every vaccination must in any case include, *inter alia*, information about the illness to be prevented, any possibilities to treat the infectious disease, advantages of the immunisation for the individual and the general public, information about the vaccine (ingredients, indicating the batch number), information about the beginning, duration of the immunisation protection and the vaccination plan, necessity of booster vaccinations, as well as the conduct after the vaccination, contraindications, possible side effects and/or complications.²⁷

In addition, when using vaccines, as with all other medicines, a physician has the duty to report on unforeseen occurrences stemming from the use of medicines, side effects not yet known, the increased occurrence of known side effects, previously unknown intolerances or interactions with other medicines, etc. All relevant information and actions, provided for a patient in an adequate and timely manner, are important not only in terms of ensuring the patient's right to consent and self-determination but also in respect of supporting a better doctor-patient relationships and building greater public trust in this medical intervention.

25 „The wellbeing of a patient and his or her free will are the highest law.“

26 See Art. 19 of the Patients' Rights Act.

27 For example, see The Austrian Ombudsman Board (AOB), *Child vaccination*, Retrieved 30, May 2017, from <http://volksanwaltschaft.gv.at/artikel/child-vaccination>

4.2. Administrative law aspects

Sanitary inspection has always exercised oversight over the implementation of immunisation laws since the beginning of 1970s or even earlier (in old SFRY laws). Under the 2016 PPID Act, oversight over different measures for protection against infectious diseases (e.g. urgent disinfection measures and child vaccination) entails the same administrative proceedings and measures.

As outlined above, the Sanitary Inspection can mandate the implementation of certain measures (both within or out of the healthcare system) to patients and their legal guardians (since these cases often involve minors). The inspector passes a ruling in an administrative procedure regulated by the 2016 PPID Act, as a *lex specialis*, alongside with the Act on Inspection Oversight and the GAP Act. In that, the PPID Act envisages two important exceptions from the general administrative procedure regime: a shorter deadline for appeal and the exclusion of its suspensive effect. It should, however, be noted that such solutions are not a novelty. The same provisions were envisaged in the former 2004 PPID Act (Art. 43), as well as the 1989 PPID Act (Art. 40 para. 2).

The same exceptions from the GAP Act apply regardless of the type of measures mandated by the Inspection's ruling and its addressee. Thus, the same administrative appeal deadline and exclusion of its suspensive effect apply to a healthcare institution or a physician that do not implement immunization, as well as to parents who, for whatever reason, challenge the need for compulsory vaccination of their child.

Hence, one could ask which specific reasons for such urgency in execution of repressive measures exist in cases of compulsory vaccination of individual children. It is clear that such reasons exist, for instance, in case of epidemics endangering the whole population. However, since deadlines in administrative procedure as defined by the GAP Act are already short enough, it is questionable if the same reasons could be related to all diverse situations covered by PPID Act.

Examples of shorter appeal deadlines are not rare in administrative law, while the exclusion of the appeal's suspensive effect is less frequent (Tomić, 2017: 556). It is customarily envisaged in cases where it is possible to **restore the prior situation**, if the appeal is justified (e.g. money paid on the account of an unlawful tax ruling). In case of vaccination, if a decision were forcibly executed (which is in theory possible according to the GAP Act provisions on administrative execution), such a reversal certainly would not be possible.

The Inspection Oversight specifically regulates that the exclusion of appeal's suspensive effect is possible if it is in accordance with the specific inspection competence and necessary in case of urgent measures to prevent dangers for,

inter alia, life or health of people (Art. 39). This general provision has been transformed into a general rule in case of Sanitary Inspection's rulings according to PPID Act.

In relation to the above, a question is thus posed: in case of postponement of a child's vaccination for another two months, which is the maximum duration of second instance administrative procedure (Art. 174 GAP Act), is the risk for the population so grave that it necessitates the demand to forcibly execute the first-instance ruling of the Inspection? Secondly, does the exclusion of the appeal's suspensive effect (added to the possibility of forcible execution which can be initiated by the first instance inspection itself) in a way make the very idea of appeal pointless.

Related to execution, the Act does not go beyond the GAP Act rules on administrative execution which apply here since compulsory vaccination of a child is a non-pecuniary obligation on the part of the parents. It is, however, unclear how execution would actually be forcibly undertaken, i.e. how a child may be vaccinated by force.

Case law, perhaps fortunately, does not provide answers to these questions since it does not include examples of forcible execution of the Sanitary Inspection rulings in case of compulsory child vaccination. The Administrative Court has not voiced itself on this issue either, not even on the principal level.²⁸

Finally, in terms of the enrolment in educational institutions, since the adoption of the 2016 PPID Act, there were some cases of children rejected for enrolment in kindergartens. However, no cases concerning primary schools have been reported so far, given the fact that the first generation of children who are to be subject to this Act started school in September 2017. It should, however, be noted that this provision should be viewed from the perspective of the obligatory character of primary education prescribed by the Constitution (Art. 71), as already deliberated in some other European countries²⁹, as well as from the perspective of the legislation in the field of education, which does not yet contain corresponding provisions for any level of education.

28 For instance, in a rare decision concerning vaccination, the Administrative Court simply states that compulsory vaccination does not demand consent of the vaccinated person or the legal guardian, Judgement of the Administrative Court, II-9 U 11958/2015 of October 20, 2015.

29 For instance, the Czech Constitutional Court held that such an obligation is not an unconstitutional limitation of the right to education as guaranteed by the Czech Constitution. See: Pl. ÚS 16/14 of 27 January 2015, Compulsory Vaccination as Condition for Admission to Kindergarten, Czech Republic, Judgment of the Constitutional Court in the name of the Czech Republic, para 107.

4.3. Family Law Issues

In addition to the limitation of the patient's right to self-determination, compulsory vaccination seems to have recently raised another important family law controversy - the old discussion about the limits of family autonomy, including parental rights, versus the right of the state to intervene in family relations. This issue was particularly supported in previous years with several announcements of the Ministry of Health officials in the media³⁰, concerning the possibility that parents who oppose vaccination could be deprived of their parental rights on the basis of child neglect. These quite disturbing statements, lacking explicit legal ground, have only increased already existing parents' concerns related to vaccination of their children and, unfortunately, once again confirmed the primarily repressive course that our state is taking in relation to this certainly important public health issue.

It is obviously forgotten that all parents have the right and obligation to care for their child.³¹ Therefore, parents are obliged to make decisions about the child always minding the child's best interest, a comprehensive legal standard which can only be appropriately evaluated based on the circumstances of each specific case. Related to this, it must be emphasized that majority of parents love their children and want only best for them. In light of the fact that vaccines may in some cases cause severe adverse reactions, parents are naturally facing the dilemma and concerns on the vaccine safety, caring for the welfare of their child, because they are either unaware of or have doubts about the available scientific evidence.³²

In these cases, in addition to the state obligation to secure the public welfare, the state also has the responsibility to address parents' concerns complementary to the strength of parents' convictions. It is important to achieve this through adequate and continuous individual and public education activities, by providing parents with all needed information in each specific case, and addressing the risks of their decisions. Furthermore, any state intervention must take into account all relevant circumstances, particularly when having in mind long-term consequences of limiting parental autonomy. Considering the fact that

30 See, for example, Blic online, *Šta sadrži novi zakon: Šest važnih pitanja o vakcinaciji*, Retrieved 15, April 2017, from <http://www.blic.rs/vesti/drustvo/sta-sadrzi-novi-zakon-sest-vaznih-pitanja-o-vakcinaciji/mejp8y8>; RTS, *Vakcinacija dece izmedju zakona i roditelja*, Retrieved 15, April 2017, from <http://www.rts.rs/page/stories/ci/story/124/drustvo/1894970/vakcinacija-dece-izmedju-zakona-i-roditelja.html>.

31 See Art. 68 of the Family Act (Porodični zakon, *Sl. glasnik RS*, 18/05, 72/11 and 6/15).

32 This is only confirmed by recent controversy surrounding association between the MMR vaccine and autism.

deprivation of parental rights represents the most severe family law sanction³³, which also affects the child, such a measure should be used with caution and be executed only in cases where all relevant circumstances are considered to meet the requirements for an omission to provide proper care, in accordance with the relevant family law regulations.³⁴ Any other approach to the issue of vaccination refusal carries the risks of further decrease of public confidence and cooperation, and only undermines the true potential of immunisation programs.

All previously stated is not to say that we cannot envisage some extreme situations in which there may be a need to protect the child by overruling and limiting parental autonomy. However, when considering the ultimate standard of the best interests of the child, as well as one of the most important rights of every child – the right to live in a family and be cared for by parents before all³⁵, these situations could only be envisaged as an exemption, not as a rule. Fortunately, in our recent family law practice, we have not found any case in which the court has decided on the deprivation of parental rights exclusively based on the fact that parents have refused to vaccinate their child. Additionally, it seems that professionals in the social work centers are currently not considering to follow the announcements of the ministry officials in their everyday practice. This gives hope that the existing family law measures (both preventive and repressive), mainly imposed within the scope of guardianship authorities³⁶, would in time be used to primarily address parents' concerns related to compulsory vaccination, by supporting them to make decisions which serve the best interests of their child and the society, and always abiding by the principle of the least intrusive intervention.

5. Concluding Observations

The provided analysis of the Serbian legal framework shows a history of a compulsory approach towards vaccination of children, with a constant increase in the number of compulsory vaccines. As a result, Serbia is among the European countries that envisage mandatory vaccination against the maximum number of infectious diseases.

33 See Art. 81-82 of the Family Act.

34 Years ago, the American Academy of Pediatrics emphasised that »Continued (vaccine) refusal after adequate discussion should be respected unless the child is put at significant risk of serious harm (as, for example, might be the case during an epidemic). Only then should state agencies be involved to override parental discretion on the basis of medical neglect« (Diekema, Committee on Bioethics, 2005).

35 See Art. 60 of the Family Act.

36 See Art. 79-80 of the Family Act.

The approach of Serbian policy makers is a dominantly repressive one. This is demonstrated through the prominent role of the Sanitary Inspection in monitoring the implementation of the PPID Act and deviations from the general regime of administrative procedure; it entails imposing misdemeanor fines in case of non-vaccination as well as the newly introduced provision making vaccination a precondition for enrolment in educational institutions. Yet, the vaccination coverage is constantly decreasing.

It seems that our legal system lacks a tailor-made approach towards children vaccination, which would take into account all the sensitivities of children as patients as well as the concerns of their parents and legal guardians when making necessary decisions. Unfortunately, we still do not have a systematized body of case law (of both administrative bodies and courts, including the Constitutional Court) which would enable a more thorough legal analysis. Current situation in terms of compulsory vaccination in Serbia also emphasizes the need for a comprehensive analysis of the PPID Act effects by the line ministry and other relevant stakeholders.

Having in mind that vaccination coverage in the past few years has dropped despite its compulsory character, it seems that instead of all coercive measures which currently shade the implementation of our immunization programs it would be valuable to try a different path with all activities that might improve state and family partnership, for the benefit of our children and society as a whole.

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Др Јелена Арсић,

Доценткиња Правног факултета,
Универзитет Унион у Београду

Др Јелена Јеринић,

Ванредна професорка Правног факултета,
Универзитет Унион у Београду

Др Јелена Симић,

Доценткиња Правног факултета,
Универзитет Унион у Београду

ОБАВЕЗНА ИЛИ ПРЕПОРУЧЕНА ВАКЦИНАЦИЈА: ПРАВНИ АСПЕКТИ ВАКЦИНАЦИЈЕ У СРБИЈИ

Резиме

Вакцинација је једно од најважнијих средстава примарне здравствене заштите. Међутим, вакцине су специфичне и разликују се од других врста медицинских интервенција, посебно због тога што представљају једну од најчешћих медицинских мера које се примењују на здраве, а не болесне особе. Њихов циљ није само добробит појединца који их прима, већ су посредно корисне и за целу популацију. Овај чланак истражује тему вакцинације деце у светлу Закона о заштити становништва од заразних болести из 2016. године. Ауторке разматрају релевантне правне аспекте вакцинације деце и анализирају потенцијални сукоб између права деце на заштиту од болести и права родитеља или законских заступника да одлучују о лечењу своје деце. Такође се истражују међународни стандарди и политике у овој области, са циљем извлачења неких закључака о адекватним правним мерама које правилно одражавале потребу за равнотежом између неопходности заштите јавног здравља и права појединаца на самоопредељење и слободу избора.

Кључне речи: *деца, вакцинација, јавно здравље, право на здравствену заштиту, право на самоопредељење.*