

## Obvezno cepljenje v Srbiji in možni spori znotraj nacionalne zakonodaje

MARTA SJENIČIĆ

**Povzetek** Nevarnost nalezljivih bolezni ne pozna meja in lahko predstavlja nevarnost za mnoge države. Kot članica SZO, ima Srbija obveznost harmonizacije njene ureditve in aktivnosti z International Health Regulations. Kot ukrep preprečitve pred nalezljivimi boleznimi, je ureditev cepljenja prepuščeno nacionalnim zakonodajam. Srbija je implementirala, desetletja, obvezno cepljenje proti določenim boleznim z namenom, da varuje javni interes in da oblikuje verigo kolektivne imunosti. Na drugi strani, nekateri državljani se sklicujejo na posameznikovo pravico, da odloča od svojem življenju in da zavrne medicinski ukrep. Ključni izzivi so, kako razlagati nacionalno zakonodajo in katere ukrepe sprejeti, da se doseže sprejemljiva precepljenost, ter tako zaščiti javni in posameznikov interes.

**Ključne besede:** • communicable diseases • prevention • immunization • national regulation • compulsory • measures •

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## Compulsory immunization in Serbia and potential conflict within national legislation

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**Abstract** Danger of communicable diseases doesn't recognize borders and can represent danger for number of states. As a member of WHO, Serbia has the obligation to harmonize its regulation and activities, with IHR. As a measure of communicable diseases prevention, immunization is left to the national legislations for regulation. Serbia has been implementing, for decades, compulsory immunization against certain diseases, in order to protect public interest and to form chain of collective immunity. On the other side, some citizens allude to the individuals' right to decide on their own life and to reject medical measure. The crucial challenges are how to interpret national legislation and which measures to undertake to achieve acceptable immunisation coverage, in order to protect public and individual interests.

**Keywords:** • communicable diseases • prevention • immunization • national regulation • compulsory • measures •

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## 1 Introduction

Public-health emergency of international concern (hereinafter: PHEIC) is defined by the International Health Regulations (hereinafter: IHR) as an extraordinary event which constitutes a public health risk to other States, through the international spread of disease and which potentially require a coordinated international response (International Health Regulations, 2005: 9). Through IHR, World Health Organization supports the State Parties in the common work aimed to save the lives from internationally spread diseases and other health risks. State Parties have their national legal acts which regulate the way of reporting in emergency situations which constitute the public health threat for the country. One of such emergency situations is spreading of communicable diseases. Danger of communicable diseases doesn't recognize borders and can represent danger for number of states. However, measures of prevention of communicable diseases are left to each national legislation to be regulated. One of these measures is immunization against communicable diseases. Serbian law regulating this issue is *Law on the protection of population from communicable diseases* (Official Gazette RS, no. 15/2016) (hereinafter: Law). Law prolongs the tradition of the laws previously on force, since it regulates in the Article 85, paragraph 1, bullet 6, fine for natural person which refuses the compulsory immunization prescribed by the Article 32 of the Law. Provisions of the Article 32 regulate that immunization shall be performed by the immunological medicaments, and that compulsory immunization of the persons of certain ages, as well as of other persons determined by the law, cannot be refused neither by the person that should be immunized, nor by the parent, i.e. guardian, except due to existence of medical temporary or permanent contraindication, which shall be determined by the medical specialist or expert team for contraindications. This is the change comparing to previous versions of the *Law on protection of people from communicable diseases* which, firstly, contained the provision that the immunization is compulsory, and from 2015, the provision that compulsory immunization "does not require written consent of the person, legal representative of the child, i.e. person deprived from legal capacity". This "adding" to the compulsory nature of immunization was very much provoked by the attitude of participants of the antivaccination wave, which called upon the *Law on patients' rights*, while refusing immunization. Otherwise, "compulsority" of immunization was quite enough to explain its nature, without the need to emphasize it further.

## 2 Relation between right/obligation to immunization and the right to education

Unlike previously valid laws, the current Law conditions the children stay in kinder gardens, schools, and homes for children without parental guardianship, with the fulfilled obligation of immunization against TBC, diphtheria, tetanus, pertussis, children paralysis, morbila, rubella, mumps, viral hepatitis B, diseases invoked by hemophilus influenza type B, and diseases invoked by streptococcus pneumonia. The exception can exist only in the case of medical contraindication determined by the medical specialist or expert team for contraindications. *Rulebook on immunization and the way of protection with medicines* (Official Gazette RS, no. 88/2017: Article 9) regulates general and special

contraindications. General contraindications for active immunization are: 1) acute illnesses, 2) febrile status; 3) anaphylaxis to components of vaccines; 4) serious adverse event to the previous vaccine dose. Beside these contraindications, contraindications to the application of live virus vaccine are: 1) status of the reduced resistance (immunodeficient status due to: malignant diseases, therapies with antimetabolics, increased doses of corticosteroids, alkylating units or radiation and other determined statuses of immunosuppression); 2) pregnancy. These contraindications do not refer to immunization of exposed or injured persons against rabies, hepatitis B and tetanus, except anaphylaxis to components of vaccines against rabies, hepatitis B and tetanus, when exclusively hyper immune globulin is given. Special contraindications are: 1) for vaccine against TBC (BCG) damage of cell immunity due to HIV infection and other causes; 2) for pertussis: evolutive illnesses of central nerve system (uncontrolled epilepsy, infantile spasms, progressive encephalopathy).

Law conditions stay in school and preschool institutions with fulfilled obligation of compulsory vaccination, but, participants of antivaccinal wave call upon the Article 71, paragraph 2 of the *Constitution of RS* (Official Gazette RS, no. 98/2006) which guarantees the right to education and, also, determines the obligation of primary education. Right of every person to free and qualitative primary education in public school is prescribed by the Article 4 of the *Law on the primary education* (Official Gazette RS, no. 55/13). Parents belonging to antivaccinal movement claim that the right of their children to education is jeopardized by the Law. In this sense, it is not easy to reach understanding on compliance between *the Law on protection of population from communicable diseases*, and other mentioned regulation that emphasizes other rights of individuals. Compulsory vaccination is imposed in individual, but also in general interest and also for the protection of the right to health, which could be considered as prevailing over the right of the individual to education. Besides, the Law conditions the *children's stay in kinder gardens, schools, and homes for children without parental guardianship (and not their access to them)*, with the fulfilled obligation of immunization. So, parents and other legal representatives are free to enroll (administratively) unimmunized children into schools and kinder gardens, but children are not free to attend these institutions, as long as they are not immunized. Their individual right to education is weaker than individual rights of the group of other children, i.e. public interest to be healthy and free from communicable diseases.

### **3 Relation between right/obligation to immunization and the right to self-determination**

In 2013, the *Law on patients' rights* (Official Gazette RS, no. 45/2013) was passed. It encompasses most of the rights that were already contained in the *Law on Health Care*. However, the diapason of the rights is also widened and the rights, somehow, became more visible to the citizens. Beside rights, *Law on patients' rights* regulates also the duties of the patients. Article 33 of the *Law on patients' rights* regulates the liability of the patient for personal health, i.e. during realization of health care, patient is obliged to: 1) actively participate in protection, maintaining, and improving of his health; 2) inform

fully and thrutfully the health professional on his health status; 3) follow the instructions and undertake measures prescribed by authorised health professional.

It seems that, with passing the *Law on patients' rights*, patients became more aware that they can refuse every medical measure that they do not agree with. Article 15, paragraph 2 of this law prescribes that no medical measure can be undertaken on a patient's body, without his consent. Paragraph 2 of the same Article, enables the exception from this rule, in the cases when life and health of other people are directly jeopardized. Compulsory immunization is one of these exceptions determined by the law, in public interest, i.e. in the interest of public health. As many people as possible are immunized, as more efficient will prevention of spreading of communicable diseases, will be. The purpose of vaccination is not to protect only individuals, but to form the chain of the immunized people, which reduce or even fully prevent the spread of communicable disease (Radišić, 2006: 1693). Vaccination, creating immunity to the diseases provoked by viruses or bacteria, is undoubtable one of the most cost effective and available measures for preservation of the populations' health. Through systematic vaccination, some hardly curable diseases, as variola vera and children paralysis, are eradicated in Europe.

However, participants of antivaccinal wave call upon the Article 15 of the *Law on patients' rights*, according to which patient capable for reasoning has the right to decide on his own life, i.e. to refuse proposed medical measure, even in the case that it would save his life. Authorized health professional is obliged, according to the Article 17, paragraph 2, to point to the consequences of such decision to the patient, and to ask written statement on the refusal from the patient. Such statement should be kept in the medical records. If patient refuses to sign the statement, the official note on this should be made. Health professional shall note in the medical records information on patients' (legal representatives') consent to medical measure, as well as the information on refusal.

When it comes to the child or person deprived from legal capacity, according to the Article 19 of the *Law on patients' rights*, medical measure can be undertaken with the informed consent of his legal representative. Health professional is also obliged to enable to the child or person deprived from legal capacity to be involved into the decision making on giving consent to medical measure, in line with the level of his maturity and capacity for reasoning.

On the other side, contemporary practice shows that physicians in some cases inform Center for social work, if parent refuses vaccination of the child. They call upon the Article 19, paragraph 3 of the *Law on patients' rights* (as to the legal basis), which regulates that "authorized health professional which believes that legal representative does not act in the best interest of the child or person deprived of legal capacity, is obliged to inform immediately competent guardianship body". This makes a sort of penalty for parents, as the information to the guardianship body is kind of pressure through threaten that the child could be taken away from parents, caused by their negligence. So, different regulation has provisions standing for, at the first glance, contradictory rights. Right of individual and public to health and lack of communicable diseases is "contrary" to the

right to self-determination towards own health and body and right to consent to medical measures. However, it is always about balancing the rights. No right is absolute – the right of each person is limited by the right of other person or general interest. Going out of these limitations may constitute not using, but abusing of rights. Therefore, the listed rights are not opposite to each other, but it is the matter of the correct legal interpretation of the laws and the right balancing.

#### 4 Measures to be undertaken

The most common reasons of non-immunization are the illness of the child, tardiness of the parents, and fear from adverse events of vaccination. Parents mostly receive the information on vaccination from pediatricians, some of the parents read expert literature, while some of them gain the knowledge on vaccination through media channels. High educated parents are more often willing to let their children be immunized with recommendable vaccines. In the population with higher education level, the attitude of parents toward immunization is very positive, which results with the high level of regular immunization (Šterić, Štrbački, Kisić-Tepavčević, 2007: 30). Therefore, it is necessary to focus the attention to the promotion of health and health education of population. In the Article 18, paragraph 1, *Law on Health Care* (Official Gazette RS, nos. 107/2005, 72/2009, 88/2010, 99/2010, 57/2011, 119/2012, 45/2013, 93/2014, 96/2015, 106/2015, 13/2017 and 105/2017) prescribes that the RS shall provide, as the public interest in health care:

- 1) monitoring and studying the conditions for life and work and health status of population, i.e. certain groups of population, causes of phenomenons, spreading and the way of prevention and suppression of diseases and injuries with higher socio-medical significance;
- 2) promotion of health in line with the programs of health care and providing of conditions for conducting of special programs for maintaining and improvement of health;
- 3) conducting of epidemiological surveillance and organising and conducting of special measures for protection of population from communicable diseases, conduction of extraordinary measures in line with the *Law on protection of population from communicable diseases*, as well as conducting of programs for prevention, suppression, and eradiction of communicable diseases in line with the law;
- 4) prevention, suppression and extinguishing outbreaks of communicable diseases.

*Law on health care* regulates socially responsible attitude of the individual obliging him to undergo obligatory vaccination in international traffic, against certain communicable diseases determined in *Law on protection of population against communicable diseases*, as well as to bear the costs of such kind of vaccination (Article 15 of the *Law on Health Care*). *Rulebook on immunization and the way of protection with medicines* regulates that conducting of measures for prevention and suppression, as well as eradication of certain communicable diseases shall be determined with special programs, plans and expert-methodological instructions, in line with the Law (Article 14 of the Rulebook). Rulebook

prescribes that health institution conducting immunization provides the continuous education of the health professionals implementing immunization, of at least 6 points during three years in the immunization area, in line with the *Law on health care* (Article 23 of the Rule book). Beside the subjects mentioned in the Rulebook, considerable number of subjects relevant for protection of population from communicable diseases are prescribed in the *Law on health care*, which includes private practice, system of the institutes for public health, Institute for virusology, vaccines and serums, Institute for antirabic protection, and institutes for biocides and medical ecology (Articles 6, 121, 126, 127 and 129 of the *Law on health care*). These provisions are the proof that legal system is quite focused to the protection of population from communicable diseases regulating the obligations of different subjects in this area.

Many countries have compulsory immunization against some diseases, but in some countries it is recommendable, and left to the individuals to decide whether to immunize or not. However, the level of immunized population is still high, and this is achieved through different measures. In certain countries, as Austria, expenses for national plan for children vaccination, encompassing the most important vaccines for infants and school children, are financed from public funds, i.e. they are free for patients. Vaccination against morbila is free for all inhabitants of Austria. Austrian laws support government agencies to promote vaccination. In Great Britain there is no compulsory vaccination, but it is voluntary and performed on the basis of informed consent of the patient. Besides, Great Britain holds the Vaccine Damage Payments Act from 1979, which regulates that if a person is severely disabled as a result of vaccination against any of diseases to which this Act applies<sup>1</sup> and under certain other conditions, damaged person or his representative. will be entitled to certain sum or benefit (McHale, Fox, 2007: 221).

In other countries, as Belgium, specific vaccinations are necessary as the condition for performing certain jobs and work in public institutions. The following factors contribute to the increase of vaccination rate in Belgium:

- a. there are available free vaccines for citizens, which are recommended in accordance with the basic vaccination prescribed Federal high council for health for children up to 18 years (these vaccines are bought by the competent bodies of the territorial administrative units);
- b. necessary doses of the mentioned vaccines are available to population in physicians offices without pharmacists mediation;
- c. extensive informing of health workers and target groups on recommendations of the Federal high council for health (pamphlets, brochures, radio and TV spots).

In ex-Yugoslav countries, systems are similar: they are quite strict and scope of vaccines that are compulsory is quite wide. Immunization is mostly mandatory for nine communicable diseases. Exceptions are allowed on the basis of medical contraindications. Beside criminalization of refusal of vaccination, there is a line of noncompulsory measures that can be undertaken in order to increase to immunization coverage. Patient should be give the information on vaccine, the thorough personal and

family anamnesis should be taken in order to determine non/existence of temporary or permanent contraindications to immunization. Besides, there are also different promotion, public campaign and education measures that could be undertaken in order to increase immunization coverage, by parallel respecting human rights of citizens. Also, increased surveillance over adverse events of immunization, prescribing liability and possibility of damage compensation by the state in the case of hard adverse effects of immunization (where there are adverse events, according to criteria determined by the medical expertise), forming special funds for damage compensation of such damages.

One decision of the Supreme court of Slovenia goes in this direction: „*If the compulsory immunization was performed against certain communicable disease, individuals that suffered the damage due to the vaccination can require compensation from the state body that ordered compulsory vaccination. Right to damage compensation is, in this case, not conditioned by anyone's fault*” (Decision of the Supreme court of Slovenia, Pž. 324/77, from 19.5.1977).

Of course, if the immunisation is voluntary, in the case of damage, vaccinated person or its legal representative overtakes the inevitable risks, if it the person/legal representative was properly informed to the risk related to immunisation. If such information is lacking, risk and damage compensation will be born by physician or health institution. In this case damage is done on health or body, and has permanent character (Deutsch, 1998: 1054). So, in this sense, one of the measures for promotion of immunisation is transparent and functional system of compensation of potential damages.

Furtheron, it is necessary that the medical profession continuously works with the media representatives, to point out hard consequences of nonvaccination, need for quoting reliable and expert sources during media reporting, and providing of media space for professionals whose attitude can support public interest (Sjeničić, Miljuš, Milenković, 2016: 332).

There are also proposals to oblige parents refusing the vaccination of the child, to pay additional insurance as coverage for risk of diseases and jeopardizing of others due to reduced coverage, until adulthood or positive decision on vaccination; another proposal is to establish compensation fund for the case of significant adverse events of vaccination; further, to protect the physicians implementing the compulsory program of immunization, from liability in this area; to conduct continuous education and to be present with the key information on vaccination at physicians office, parents, and the whole publicity.

Beside the possibility to introduce these alternative methods of influence to parents that refuse vaccination of their children without legally and medically relevant excuse, in Serbia stays on force provision of the Article 85 of the Law, regulating the fining of natural person refusing the compulsory immunization of the persons of certain age. Of course, it would be good to implement the experiences of the states which pay more attention to campaigns and promotions of health, as well as informing of health workers and target groups on positive effects of vaccination. And it is necessary to conduct



continous education of pediatrians related to the need of giving explanation to parents, promotion of immunisation, and carefull examination of children before vaccination, for the purpose of determining existance of contraindication to vaccination.

## 5 Conclusion

Vaccination is necessary in individual, but also in general interest for the purpose of forming of chain of immunised persons, which prevent spreading of communicable diseases. Due to physiological differences, immunisation is not possible for all the citizens. If the state accepts the compulsory immunisation system, it should stick to it without legislative vacillations. Solution should not be extrem, but should be acceptable from the point of public interest, and also of individuals. On one side, patient has the right to refuse indicated medical measure, whilst, on the other side, state has the public interest to prevent spreading of disease. In most of the cases these two interests are not contradictory, and where they are, one should tend to bring them in compliance through appropriate measures, which should be promotonal and educattional above all, and only after that – compulsory measures. No one of these rights, interests, is absolute. They are relative. Individual can use its right as long as he doesn't jeopardise the rights of other people. Also, state conducts mandatory immunisation until it jeopardise health and life of individual. In order to implement all these goals, the following is necessary: strong public campaign on the necessity of immunisation, thorough examination of people to be immunised, continous education of professionals on vaccination, continous rechecking of medical standards on the necessity of immunisation against certain diseases and on safety of certain vaccins, and last but not least, hearing for the voice of medical expertise, but also of the publicity.

### Note

<sup>1</sup> Act applies to: diphteria, tetanus, whooping cough, poliomyelitis, measles, rubella, tuberculosis, smallpox and any other disease which is pecified by the Secretary of State for the purposes of this Act by order made by statutory instrument.

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