

No. U-I-127/01

Date: 12 February 2004

D E C I S I O N

In proceedings to decide on the petitions of the SVOOD Society for Freedom of Decision-Making, represented by President of the Society Aleš Lavrič, and others, at the session held on 12 February 2004, the Constitutional Court

d e c i d e d:

1. Art. 22.1.1, Art. 57.1.4, and Art. 57.2 of the Infectious Diseases Act (Official Gazette RS, No. 69/95) are not inconsistent with the Constitution.
2. The Infectious Diseases Act is inconsistent with the Constitution, as it does not regulate a procedure and the rights of affected persons in connection with establishing justified reasons for excuse from compulsory vaccination, and does not regulate liability for damages of the state for a damage that an individual suffers due to compulsory vaccination.
3. The National Assembly must remedy the inconsistency established in the previous indent in one year from the publication of this decision in the Official Gazette of the Republic of Slovenia.

R e a s o n i n g

A.

1. The petitioners challenged Art. 22.1.1, Art. 57.1.4, and Art. 57.2 of the Infectious Diseases Act (hereinafter ZNB). According to the petitioners, the obligation to undergo vaccination violates fundamental human rights guaranteed in the Constitution, as well as the violation of the fundamental principle of medical ethics, i.e. the principle of free consent to a medical intervention. The emphasized that vaccination is a medical intervention which is not intended for medical treatment, as healthy children are vaccinated. Certain vaccines allegedly contain very poisonous substances which by entering the body can permanently damage the health of the vaccinated person in different persons. The petitioners also warned that different vaccines can cause different responses, and that antibodies are not always created. In the opinion of the petitioners, vaccination as a preventive health measure does not at all protect a vast number of vaccinated persons. Besides, modern medicine cannot envisage all the consequences of vaccination in individuals. According to the petitioners, the provision of Art. 22.1.1 of ZNB is contrary to the right to the inviolability of human life (Art. 17 of the Constitution), as for certain individuals vaccination is very dangerous and cause in them permanent disability and even death. In the words of the petitioners, modern medicine namely does not know the method according to which it could predict the individual's reaction to a certain vaccine. If vaccination can cause the death of a vaccinated person, it is inconsistent with Art. 17 of the Constitution. The challenged statutory provision allegedly contradicted also Art. 18 of the Constitution, which prohibits the conducting of medical or

other scientific experiments on any person without their free consent. The petitioners asserted that the provision of Art. 22 of ZNB allows for compulsory medical experimentation. According to the petitioners, the majority of vaccines which are massively used are insufficiently tested, their testing groups are small, and the time of observation is too short for the producers of vaccines and medical authorities to be able to evaluate the true quality, safety, and effectiveness of a vaccine, and establish rare, however serious, side effects of vaccination. In addition to that, certain unregistered vaccines were allegedly in use. The testing of the safety of vaccines prior to registration is, in the opinion of the petitioners, very limited, and there are not enough data available for the carrying out of an independent research. The petitioners pointed to the incompatibility of interests, and the inappropriateness of procedures for the approval of vaccines, the formation of recommendations for vaccination, and the import of vaccines. The Institute for Health Care of the Republic of Slovenia (hereinafter the IVZ) is namely the importer, distributor, and proposer of the issuance of a permit for sale for all vaccines that appear on the market in Slovenia. At the same time, the IVZ forms recommendations for vaccination and supervises such. The IVZ thus issues recommendations and carries out vaccination, which is, in the opinions of the petitioners, completely incompatible with the distributor's (commercial) function. The petitioners asserted that vaccination can cause a serious and untreatable damage to health (e.g. damage to the immune system, neurological damage, encephalitis, developmental disturbances, and mental retardation, etc.). Besides that, a certain number of vaccinated persons in whom antibodies are not developed do not benefit from that in any respect, but only take a risk. As physicians cannot envisage possible complications in individuals, and as vaccination can cause a permanent damage to health or even death, according to the petitioners, compulsory vaccination is also inconsistent with the right to personal dignity and safety (Art. 34 of the Constitution).

2. The petitioners asserted that Art. 22.1.1 of ZNB also interfered with human mental dignity, as it denies patients or the parents of minors the right to decide on them (Art. 35 of the Constitution). They argued that prior to vaccination physicians generally act without an explicit consent by parents, as they act according to an instruction of the national coordinator, who in the booklet Vaccination – Instructions and Recommendations states that the consent of parents is not necessary as they allegedly give their consent by coming to a medical center. In accordance with the petitioners, the law which prescribes compulsory vaccination does not exclude the provisions of other laws, particularly the provisions on the conscious consent of a patient to every medical intervention, the possibility of refusal, and the duty of a physician to explain an intervention prior to its carrying out. The petitioners asserted that in the event of compulsory vaccination 51.3 of the Constitution, which provides that no one may be compelled to undergo medical treatment except in cases provided by law, was not applicable. They namely asserted that vaccination cannot be defined as medical treatment since healthy people are vaccinated. If even sick people cannot be forced to undergo medical treatment (except in cases provided by law), according to the petitioners, there are even fewer reasons for compelling healthy people to undergo a potentially dangerous interference with their physical integrity and health. All the more so since vaccination is particularly intended for children who enjoy a special protection by the state, pursuant to the Constitution (Art. 56 of the Constitution). Even if vaccination was understood as medical treatment in a broader meaning, Art. 22 of ZNB would mean a too excessive interference with other human rights and fundamental freedoms ensured in Arts. 17, 18, 34, 35, and 56 of the Constitution. The petitioners opined that the case at

issue concerned a too excessive limitation of the mentioned rights, which is not needed to ensure the rights of others. The voluntary character of vaccination does not limit the right of others to be vaccinated and, in such a manner, protected against infectious diseases. The petitioners emphasized that vaccination does not ensure absolute safety from a disease even to a vaccinated person, thus also 95 % vaccination coverage cannot ensure absolute safety to those who remained unvaccinated due to given contraindications. In particular due to the provision of Art. 15 of the Constitution, compulsory vaccination cannot be imposed on those who do not want to undergo such as they consider vaccination as a too great personal risk.

3. The petitioners argued that the challenged statutory provision made possible or even enacted abuse of children, which is inconsistent with Art. 56 of the Constitution. They emphasized that vaccination must be to a child's immediate benefit, and not a measure to protect others. As an example they stated rubella, which is a mild and harmless disease, potentially dangerous only for women in the first three months of pregnancy. In one-year and six-year children which are the target group of compulsory vaccination against rubella, far more serious medical complications can occur than those caused by rubella. Vaccination against rubella does not bring any immediate benefit to the mentioned children (particularly boys), but is, according to the petitioners, only a measure to protect others. An equal violation of children's rights allegedly also occurs in the event of compulsory vaccination against mumps, which is a mild and harmless disease of children, potentially dangerous only for men in the post-puberty period. In the petitioners' opinion, the target group of such vaccination should only be non-immune boys after puberty, by no means all one-year and six-year children, including girls. Furthermore, the uncritical decision to introduce compulsory vaccination against *Haemophilus influenzae B* (Hib) bacteria and against hepatitis B was allegedly contrary to the rights of children under Art. 56 of the Constitution. In the opinion of the petitioners, illness due to these two diseases is namely rare such that the introduction of compulsory vaccination is not justified. The petitioners warned that in Slovenia hepatitis B is such a rare disease which endangers only adults and is transmitted only in cases of risked activities. The regulation of compulsory vaccination against rubella, mumps, and hepatitis B is, in the opinion of the petitioners, contrary also to Art. 6 of the [Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine](#) (Official Gazette RS, No. 70/98, MP, No. 17/98 – hereinafter MVCPB), which provides that an intervention may only be made concerning a person who is capable to give consent, and only to their immediate benefit.

4. The regulation of compulsory vaccination entails an interference with certain human rights and fundamental freedoms, thus, in the opinion of the petitioners, such interference must be evaluated from the view of the principle of proportionality. The petitioners opined that compulsory vaccination is not an appropriate measure, as it offers no absolute protection to those vaccinated, and even less to those unvaccinated. They emphasized that hitherto vaccination has not eradicated any infectious disease, but the majority of infectious diseases disappeared from developed countries for reason of improved general hygiene. Besides, vaccination allegedly does not prevent a disease, but only changes the typical clinical symptoms due to which diseases receive different names and thus disappear from statistics. The interference with the constitutionally protected values of an individual is, according to the petitioners, not necessary, since the majority of European countries only recommend vaccination, and does not prescribe

such as compulsory. This allegedly demonstrated the fact that goals desired can be achieved in other manners. In the opinion of the petitioners, compulsory vaccination as prescribed by 22.1.1 of ZNB is an excessive measure, as the compulsory program of vaccination for children is too extensive and prescribes vaccination also against diseases which do not threaten the life and health of children. Moreover, vaccination is prescribed for all children, not only for those belonging to risky groups. The petitioners were against the regulation due to which all must be vaccinated to protect a small number of unvaccinated persons who do not undergo vaccination for reason of their health condition. Among such there are many who do not benefit from vaccination, and are thereby only exposed to risks. In the petitioners' opinion, compulsory vaccination simply limits too many constitutional rights, including those that cannot be limited according to the Constitution (e.g. the inviolability of life – Art. 17 of the Constitution).

5. In the opinion of the petitioners, compulsory vaccination entails also a violation of the fundamental principle of modern medical ethics, i.e. the principle of conscious consent of a patient to a medical intervention, which is recognized both in Art. 5 of MVCPB as well as in the valid legislation, i.e. in Art. 47 of the Medical Activities Act (Official Gazette RS, No. 9/92 et seq. – ZZDej) and Art. 47 of the Medical Service Act (Official Gazette RS, No. 98/99 et seq. – ZZdrS). According to the petitioners, conscious consent is a prerequisite for every ethical medical intervention. What is necessarily connected with the concept of conscious consent is the explanatory duty of physicians, who are in every instance obliged to thoroughly inform every vaccinated person (or their statutory representative) of the procedure for vaccination and of possible risks and complications, and may carry out vaccination only if the patient or their statutory representative explicitly consents to such. The petitioners pointed to the booklet issued by the national coordinator of vaccination (Vaccination – Instructions and Recommendations), in which it is mentioned that no consent is needed for compulsory vaccination, as parents give their consent to vaccination already by coming to a medical center together with their children. The petitioners did not agree to such a position, as they opined that parents must be thoroughly informed of every medical intervention regarding a child, and must give their explicit consent prior to every intervention. In the opinion of the petitioners, the provision of Art. 22.1.1 of ZNB is inconsistent with Art. 5 of MVCPB.

6. The petitioners warned that according to the present statutory regulation no one is responsible for the course of vaccination and possible side effects and consequences. They opined that Art. 22.1.1 of ZNB limits physicians and their professional judgment concerning the appropriateness of vaccination regarding every individual, and releases them from responsibility for the consequences of vaccination, as in giving a vaccine a physician becomes a representative of the state. Compulsory vaccination allegedly releases also parents from responsibility. In the opinion of the petitioners, the necessary consequence of such is incaution of both parents and physicians. Practice has allegedly demonstrated that physicians who carry out vaccination are not informed well enough of the effects of individual vaccines, which means that also parents are not given the entire information. The petitioners opined that the voluntary character of vaccination could entail that physicians become personally responsible for every individual vaccination, provide to the greatest possible extent for that there would be no complications, and treat endangered children with a special care. In addition to that, parents would treat vaccination with greater responsibility, and together with a personal physician try to find the most appropriate manner for the protection of their child.

7. All the mentioned concerns, which the petitioners referred to Art. 22.1.1 of ZNB, allegedly apply also to Art. 57.1.4 and Art. 57.2 of ZNB, which determine a fine if an individual avoids or makes impossible compulsory vaccination under Art. 22.1 of ZNB.

8. In its reply the National Assembly refused the concerns regarding the inconsistency of the challenged regulation with the Constitution. It explained that in no phase of the ordinary parliamentary procedure the regulation of compulsory vaccination was made problematic, neither from the side of deputies, the working body responsible, nor from the side of the professional or other public concerned. All the time during the discussion and enactment of the law, what was in the center of attention was the legislature's intention to enact all general and special measures for the prevention of infectious diseases, which the state must ensure in conformity with its general social care for the health of inhabitants. The measures also include the challenged statutory provision, which determines compulsory vaccination, and the intention of which is to ensure the highest collective immunity by means of an appropriate scope of vaccination. In order to avoid possible detrimental effects of compulsory vaccination, Art. 22 of ZNB also contains a provision which imposes on physicians carrying out vaccination the duty to previously establish possible justified reasons for excuse from vaccination, i.e. contraindications. On the existence of permanent justified reasons for excuse from vaccination, i.e. permanent contraindications, a special expert commission decides, which is established by the Ministry of Health. In the estimation of the National Assembly, all these statutory mechanisms allow for the possibility that in extraordinary cases vaccination is discontinued. Furthermore, in their opinions, the Government and the Ministry of Health (hereinafter the Ministry) refused the concerns that the petitioners addressed to the challenged ZNB provisions. They were of the opinion that vaccination is an examined and safe health measure by which a number of infectious diseases is prevented and controlled, due to which in the past children and adults had fallen ill and the consequences of which had often been disability and death. Vaccination is not only intended for the prevention of the occurrence of infectious diseases, but also for treatment. According to the Government, the petitioners' assertions on risks due to vaccination were misleading. By means of modern professional methods, medicine with great predictability foretells the movement of infectious diseases, as well as estimates a risk for the spreading of such diseases and the effects of vaccination on the individual and the population. The petitioners' assertions that some diseases have disappeared only due to improved hygienic conditions are, according to the Government, incorrect. Vaccination has importantly decreased people's illness and death due to infectious diseases. By vaccination the individual immunity is established in the first place, however, an even more important goal of such is the establishment of the so-called collective immunity, which prevents that germs in the population covered by vaccination are spread and reach those individuals who could not be vaccinated due to contraindications, or in the cases of whom vaccination was not successful. Vaccination was allegedly not only to the benefit of the individual, but all. In the event of the danger of an infectious disease, the right of the community to prevent the spreading of the diseased prevails over the right of an individual to decide on them. The balance between individual and general values in the area of protection against infectious diseases is, according to the Government, the issue regarding which the state has the right to regulate health care in a manner such that protects the health of all citizens to the greatest possible extent. Furthermore, the Ministry and the Government emphasized that a great care is devoted to safe vaccination. Only safe and quality vaccines are used, in which every series of vaccine is under special control. Additionally, prior to vaccination

the physician must establish possible contraindications and, given justified reasons, discontinue vaccination. The Ministry recognized that developed countries mostly do not determine compulsory vaccination (compulsory vaccination is allegedly prescribed only in Italy, France, Finland, Japan and in a majority of federal states in the USA), however, it thereby warned that, these states have for a longer time invested in the health education of their citizens and their care for their own health. The Ministry was of the opinion that in Slovenia the gaining of such consciousness is only at the beginning, and estimated that, given the present level of health consciousness and due to a negative campaign against compulsory vaccination, the immediate discontinuance of carrying out compulsory vaccination would entail the lowering of the proportion of vaccinated persons from the present 90–95% to 70%, or even lower. Therefore, according to the Ministry and the Government, the decision on the discontinuance of compulsory vaccination would entail an enormous risk, in particular if such begins to apply immediately and without long-term investments in citizens' gaining appropriate consciousness.

9. Replying to the opinions of the Government and the National Assembly, the SVOOD Society for Freedom of Decision-Making expressed its discontent with their positions. It repeated that the challenged ZNB provisions are unconstitutional, as the legislature did not make the inevitably necessary balancing between the constitutionally protected values which collide in this case. The unconstitutionality of the challenged statutory provisions was allegedly in that, in interfering with important constitutional rights such as the rights to life and health, the legislature did not clearly regulate the rights of affected persons or procedures in which the individual could defend their human rights and fundamental freedoms. As the challenged ZNB provisions did not regulate these essential issues, they were inconsistent with Art. 2 of the Constitution. In the opinion of the SVOOD Society, the provisions on the previous establishment of contraindications, to which the Government and the Ministry referred thereby justifying the existence of compulsory vaccination, do not suffice for an effective defense of the rights of affected persons.

B. – I.

10. Pursuant to Art. 24 of the Constitutional Court Act (Official Gazette RS, No. 15/94 – hereinafter ZUstS), everyone who files a petition for the commencement of proceedings must demonstrate their legal interest. Legal interest for the filing of a petition is demonstrated, if a regulation or a general act for the exercise of public authority, whose review the petitioner proposes, directly interferes with their rights, legal interest, or legal position. According to the established constitutional review, political parties, societies, chambers, and associations have legal interest only for the challenging of regulations which directly interfere with their rights, legal interests, or legal positions. For petitions that they file on behalf of their members and due to their interests, their legal interest is not demonstrated. Exceptionally, the Constitutional Court recognizes the legal interest for filing petitions to those associations which have been established for the very purpose of ensuring the rights and interests of a group of persons who associate with such, while a challenged regulation allegedly violates these rights (see, e.g., Decision No. U-I-86/94, dated 6 April 1995, Official Gazette RS, No. 86/94 and DecCC V, 153; Decision No. U-I-75/96, dated 14 November 1996, Official Gazette RS, No. 66/96 and DecCC V, 154, and Ruling No. U-I-190/95, dated 15 July 1999, Official Gazette RS, No. 59/99 and DecCC VIII, 95; Decision No. U-I-31/96, dated 26 November 1998, DecCC

VII, 212). Such a case is also the case of the SVOOD Society, which has been established for the very purpose of ensuring the rights and interests of parents on whom the Act imposes the obligation of the compulsory vaccination of their children. Therefore, the Constitutional Court recognized the mentioned society their legal interest, accepted the petition, and, given the fulfilled conditions under Art. 26.4 of ZUstS, continued with deciding on the merits of the case.

11. At the session dated 8 May 2003, the Constitutional Court decided to hold a public hearing in this case. Subsequently it, however, evaluated that the state of facts being the basis for the review of the constitutionality of the challenged provisions was sufficiently explained, and that additional explanation by the parties was not needed. Finally, it decided not to hold a public hearing.

B. – II.

12. Art. 22.1.1 of ZNB determines compulsory vaccination against tuberculosis, diphtheria, tetanus, whooping cough, infantile paralysis, measles, mumps, rubella, and hepatitis B. The provisions of Art. 57.1.4 and Art. 57.2 of ZNB determine a fine if an individual avoids or makes impossible compulsory vaccination determined in Art. 22.1 of ZNB.

13. Art. 51.1 of the Constitution determines the right to health care. It is a human right of a positive status, which requires from the state active operation. The state must with appropriate measures ensure the effective exercise of this human right. It must ensure by appropriate measures that individuals and inhabitants are provided necessary preventive and curative health measures, with the purpose to ensure the highest possible level of health.¹ Health care can be understood in a broader meaning (including various, also preventive, measures which have a direct or indirect positive impact on the preservation or improvement of health), or a narrower meaning of medical treatment in the event of an individual's immediate need for health care. The constitutional right to health care contains both aspects, i.e. the broader (more general) and the narrower (more concrete, if seen from the view of an individual).² Vaccination against infectious diseases is such a preventive health measure, which means medical treatment in the broader meaning, and contributes to the preservation of the health of the individual and the members of a wider community.

14. Art. 51.3 of the Constitution contains the principle of the voluntary character of medical treatment, which includes the prohibition that no one may be compelled to undergo medical treatment except in cases provided by law. The principled prohibition against compelled medical treatment derives from the position that an individual is the subject and not the object of treatment. Furthermore, the expression "medical treatment" determined in Art. 51.3 of the Constitution must be understood in a broader manner such that embraces the use of every individual medical intervention, either curative or preventive, i.e. any medical intervention. However, it is necessary to emphasize that the right to refuse medical treatment is not absolute. This already derives from Art. 51.3 of

¹ Kresal B. in: Šturm L. (ed.), *Komentar Ustave Republike Slovenije* [The Commentary on the Constitution of the Republic of Slovenia], Fakulteta za podiplomske državne in evropske študije, Ljubljana 2002, p. 547, indents 5 and 7.

² Kresal B.: p. 548, indent 8.

the Constitution which explicitly allows limitations determined by law.³ Thus, it is allowed by law to determine cases in which medical treatment can be carried out without the individual's consent or even against their (explicitly expressed) will.

15. Vaccination is one of health measures in which an interference with the physical integrity of an individual is inevitable. In connection with such there also appears the question of the patient's consent as the basic condition of the admissibility of every medical intervention, and the question of a conflict between the rights of an individual on the one hand and the public interest to ensure appropriate measures for the protection of the health of inhabitants on the other hand. By determining compulsory vaccination, the legislature evidently stemmed from that the ensuring of the health of the entire population is a more important value than the patient's right to decide on them.⁴

16. Thus, Art. 22.1.1 of ZNB (compulsory vaccination) refers to interference with certain human rights – the right of an individual to decide on them, the right to the protection of their physical integrity (Art. 35 of the Constitution), and the right to voluntarily undergo medical treatment (Art. 51.3 of the Constitution). From the view of the individual's right to decide on them, also the provision of Art. 5 of MVPCB is important, which provides that a medical intervention can only be made after a person concerned was informed and consented to such, given that such a person must previously be appropriately informed of the purpose and character of the intervention, as well as of its consequences and risks. Art. 6 of MVPCB determines the protection of persons who are not capable of giving their consent. It provides that, with due consideration to Arts. 17 and 20 of the Convention, an intervention can be made concerning a person who is not capable of giving their consent to such only to its immediate benefit. When, according to law, a minor is not capable of consenting to an intervention, the intervention may be carried out only with the permission of their representative or an institution or a person or an authority as provided by law. The opinion of minors should be regarded in proportion to their age and capacity for discernment (Art. 6.2). In the concrete case the petitioners are parents who opposed compulsory vaccination due to interference with the constitutional rights of their children. They had the basis for such in Art. 47.1 of ZZDej, which provides that parents (or custodians) should assert the rights connected with medical treatment for children up to the age of fifteen. Thus, compulsory treatment entails an interference with the mentioned constitutional rights of children who, however, given their age and capacity for discernment cannot assert such themselves, which is why parents assert such for them. Concerning such, it is necessary to point to Art. 24 of the UN Convention on the Rights of the Child (Official Gazette SFRY, No. 15/90, Act on Notification of Succession concerning UN Conventions and Conventions Adopted in the International Agency for Atomic Energy, Official Gazette RS, No. 35/92, MP, No. 9/92 – hereinafter KOP), in which special care for the health of the child is emphasized. According to Para. 1 of this article, state parties recognize the child's right to the highest achievable level of health, the services of institutions for the medical treatment of diseases, and to medical rehabilitation. Para. 2 of the same article determines that state parties shall try to fully exercise this right and to that purpose adopt appropriate measures, among which also measures for the development of preventive health care (Art. 24.2.f of KOP).

³ Kresal B.: p. 550, indent 13.

⁴ Šelih, A.: Pravni vidiki obveznega cepljenja [Legal Aspects of Compulsory Vaccination]; XI. srečanje pediatrov v Mariboru, Slovenska pediatrija, Ljubljana, Pediatrična klinika, 2000, pp. 52-54.

17. The aim that the legislature pursued in the determination of compulsory vaccination was to prevent the spreading of infectious diseases. Thereby, what was to be achieved to the highest possible extent was the protection of the individual against infection and the prevention of the occurrence of epidemics, which in the past had caused the damage of health, and in certain instances also the death of a great number of people. As it was already mentioned in Para. 13 of the reasoning, the legislature is not only justified, but also, pursuant to Art. 51.1 of the Constitution, also obliged to adopt measures by which individuals and inhabitants are entirely ensured the highest possible level of health. In this view, the legislature had a legitimate, i.e. sound and reasonable, aim to interfere with human rights. From this aspect, the interference at issue was not inadmissible as, according to the constitutional review based on Art. 15.3 of the Constitution, human rights and fundamental freedom may be limited due to the rights of others or the public benefit.

18. In addition to that an interference with human rights can only be based on a legitimate, sound and reasonable, aim, according to the established constitutional review, it is always necessary to evaluate whether such is in conformity with the principles of a state governed by the rule of law (Art. 2 of the Constitution), i.e. with the one of these principles which prohibits excessive state interferences also when a legitimate aim is pursued (the general principle of proportionality). The Constitutional Court evaluates whether there was a too excessive interference on the basis of the so-called strict test of proportionality. This test includes the review of three aspects of the interference:

(1) whether the interference was necessary (needed) for reaching the aim pursued;
 (2) whether the evaluated interference was appropriate to reach the aim pursued, in the sense that the aim is possible to be achieved by the interference;
 (3) whether the weight of consequences of the evaluated interference with an affected human right is proportional to the value of the aim pursued, or to the benefits that will occur due to the interference (the principle of proportionality in the narrower meaning). Only if the interference stands all three aspects of the test, it is constitutionally admissible. The constitutional authority vested in the legislature to limit constitutional rights (in this case the authority to determine exceptions from voluntary undergoing medical treatment) also does not entail that the legislature can determine limitations or interferences at its free will. The general constitutional principle of proportionality must be considered in every limitation of human rights and fundamental freedoms, irrespective of the basis of the legitimacy of interference.

19. In the framework of the test of proportionality, the Constitutional Court first reviewed whether the interference with the constitutionally protected physical integrity of an individual, the individual's right to decide on them (Art. 35 of the Constitution), and the individual's right to voluntary undergo medical treatment (Art. 51.1 of the Constitution), was necessary to achieve the constitutionally admissible goal, which is to prevent and control infectious diseases. As already mentioned, the state is obliged to ensure appropriate health protection against infectious diseases which can threaten the health and life of an individual or the entire population. At the same time, it is necessary to emphasize that also every individual is obliged to take care of their own health,⁵ which

⁵] Art. 4.1 of the ZNB explicitly determines that everyone has the right to protection from infectious diseases and hospital infections, and the duty to protect their health and the health of others from these diseases. On the duty to protect one's own health see also Šeparović, Z.: *Granice rizika, etičkopravni pristupi medicini* [The Limits of Risk, Ethical and Legal Approaches to Medicine]; Znanstvene monografije, Zagreb, Čakovec, 1985; p. 20.

includes the duty of cooperation in preventive measures, which are determined to the benefit of the individual and to the general benefit. In Art. 22.1.1 of ZNB the legislature determined infectious diseases against which vaccination is compulsory. In connection with the petitioners' concern that the list of these diseases is too broad, the Constitutional Court explains that the evaluation which infectious diseases present a danger for the health of the individual and the population such that they justify the determination of a measure of compulsory vaccination, must be left to the medical (or epidemiological) profession. Thus, a comparison with other countries cannot be decisive for its evaluation, as well as it is not possible to consider the assertions that there are allegedly no reasons for compulsory vaccination against certain milder infectious diseases (e.g. mumps and rubella). As it follows from the explanation of the draft ZNB (Reporter NA, No. 4/94), in the determination of the list of infectious diseases, the legislature followed the recommendation of the World Health Organization (hereinafter WHO) and the goals that WHO set in the period until 2000.⁶ By vaccination against infectious diseases the immunity of a vaccinated individual is established and, with 90–95% vaccination coverage of the population against individual diseases, also the so-called collective immunity of the population. The spreading of infectious diseases and thereby the occurrence of epidemics can be prevented only by an efficient degree of vaccination of the population. Accordingly, it is necessary that all those in whom no justified reasons were established for excuse from vaccination (the so-called contraindications) are subject to vaccination. As the Constitution itself in Art. 51.3 allows that health measures can be determined also without the consent of an individual, the legislature was allowed to prescribe compulsory vaccination as a measure for reaching the goal pursued. The petitioners did not state by which milder measure the same degree of vaccination coverage of the population can be achieved.⁷ They only assume that also if vaccination was not compulsory a sufficient number of individuals would decide for such, which is why it is not allegedly necessary for them (or their children) to undergo vaccination. As by vaccination the collective protection of the population against infectious diseases is ensured, in exercising their right to decide on them the individual cannot rely on that those who undergo vaccination will take care of protection against the spreading of infectious diseases (and thereby also of their protection).

20. There is no doubt that vaccination has importantly contributed to raising the level of the health of population, and that it has to a great extent contributed to decrease in the number of sick persons and those who die due to infectious diseases, or to that there have not been epidemics or even certain infectious diseases (e.g. diphtheria) for several years.⁸ From the strategy that WHO created for the 2002–2005 period⁹ what follows is

⁶ In the programme of the WHO – Immunization policy, Global Programme for Vaccines and Immunization, WHO, Geneva, 1996 – it is recommended that in all countries vaccination against infantile paralysis, diphtheria, whooping cough, tetanus, and measles, and also against tuberculosis (especially in countries where this disease is still frequent) and hepatitis B (this vaccination should have been introduced into the national programmes of all countries by 1997) should be provided.

⁷ A sufficient degree of the vaccination coverage of children can also be achieved with indirect measures: in a manner such that at the enrolment into school a confirmation of vaccination against certain diseases must be presented, or by limiting the reimbursement of medical treatment costs and absence from work due to a disease, which could have been prevented by vaccination.

⁸ From the information of the IVZ, which keeps a register of reported infectious diseases in Slovenia it is evident that the last case of diphtheria was registered in 1967. Also the information for other infectious diseases (e.g. infantile paralysis, whooping cough etc.) shows a steep decrease in the number of patients. From the information of the WHO, published in the report "WHO vaccine-preventable diseases: monitoring system, 2003 global summary" (published on the WHO web site: <http://www.who.int/vaccines-documents/>) it follows that the mortality rate of children due to

trying to ensure the greatest accessibility of vaccines and vaccination coverage of children as possible, all with the goal to prevent and control, as well as eradicate certain infectious diseases (one of the major goals of WHO for the period until 2005 is, e.g., the eradication of infantile paralysis). In accordance with the evaluation of the Constitutional Court, compulsory vaccination as determined by the legislature in Art. 22.1.1 of ZNB is a measure appropriate for reaching the pursued aim, i.e. the prevention and control of infectious diseases.

21. In the framework of proportionality in the broader meaning, the Constitutional Court weighs the importance of the right affected by interference against the right which is to be ensured by the interference, and establishes the weight of the interference in proportion to the weight of the rights affected. Given the review of this criterion, the Constitutional Court established that the benefit which vaccination brings for the health of the individual and the broader community exceeds the potential damage individuals might suffer due to side effects of this measure. Even if in individual cases unwanted side effects of vaccination occur, they are mostly of a milder character, which cease to exist without a medical intervention and permanent consequences (e.g. milder allergic reactions, raised temperature, and headache, etc.). Medical aid or even hospitalization is needed very rarely.¹⁰ According to experts' evaluation, the risk that an individual will suffer an impairment of health due to vaccination is essentially lower than the risk that they would face due to illness, which could cause more serious consequences than vaccination. In instances in which vaccination would pose a too great risk for the health of the individual, the Act makes possible the establishment of (permanent) justified reasons for excuse from vaccination (more on this in Para. 26 of the reasoning). The petitioners otherwise referred to certain sources from which allegedly follow that vaccination can cause serious impairments of health or even death, however, epidemiological research did not confirm the causal connection between the effect of vaccines and the impairments of health or even instances of death.¹¹ Furthermore, that in our country the number of negative side effects is relatively low follows from the statistical data of the IVZ.¹² The discontinuance of compulsory vaccination would on the other hand entail a great risk that, due to the degree of vaccination coverage falling below the critical point, infectious diseases and epidemics recur. These consequences would be for the health and life of the people incomparably greater than the risk of health problems, which only rarely occur after vaccination. Therefore, the Constitutional Court

infectious diseases in certain less developed countries (particularly in Africa) is still very high, where one of the main reasons for that is the inaccessibility of vaccines.

⁹ Vaccines, Immunization and Biologicals: 2002-2005 Strategy; published on the web site <http://www.who.int/vaccines-documents/>

¹⁰ Thus, Kraigher, A.: Cepljenje – najučinkovitejša zaščita pred nalezljivimi boleznimi [Vaccination – The Most Effective Protection against Infectious Diseases], ISIS, December 2001, pp. 54 and 55. According to the author's opinion, along decreasing numbers of patients with infectious diseases, against which they are vaccinated, every effect associated with vaccination is very noticeable and attracts the attention of doctors as well as the vaccinated persons and the people around them.

¹¹ Dr. A. Kraigher points this out in the article mentioned under Note 10. On the fact that there are no clinical or laboratory evidence of a direct causal connection between certain severe side effects (e.g. death) and vaccination speaks also Geoffrey Evans in the article: Vaccine injury compensation programs worldwide (published in the official gazette of the International Society for Vaccine: Vaccine, Volume 17, Supplement 3, Elsevier Science Ltd., 1999 and on the web site: www.elsevier.com/locate/vaccine). The author stresses that it remains unclear, which cases of injury and death can really be attributed to the effect of vaccines.

¹² The information of the IVZ on the number of side effects in Slovenia in 2000 show that in that year 248 cases were reported where the most frequent side effects were: swelling (128), redness (117), pain at the place of injection (93) and elevated temperature (89). Because of effects associated with vaccination, 19 children were hospitalized in 2000.

evaluated that the benefits that compulsory vaccination brings for the health of the individual and members of the broader community outweighs the weight of consequences of the interference with the constitutional rights of the individual. Thus, compulsory vaccination as determined by ZNB is not an excessive measure.

22. On the basis of the above-mentioned, the Constitutional Court holds that Art. 22.1.1 of ZNB is not inconsistent with Art. 35 and Art. 51.3 of the Constitution. Thereby it is also not inconsistent with Art. 5 of MVCPB, which contains the general principal of consent to a medical intervention, and with Art. 6 of MVCPB, which determines the protection of persons who are not capable of consenting. As the petitioners challenged Art. 57.1.4 and Art. 57.2 of ZNB only in conjunction with Art. 22.1.1 of this Act, the Constitutional Court established that also these two provisions are not inconsistent with the Constitution.

23. Furthermore, the challenged statutory provisions cannot be viewed as inconsistent with Art. 56 of the Constitution. The Constitution obliges the state to provide for children a special protection and care. The legislature ensures this protection by regulations in the areas of family law, labor law, social protection, and other areas. A special protection and care must be ensured for children also in the area of health care. By prescribing compulsory vaccination the legislature acted in accordance with the duty to ensure to everyone, particularly children, necessary preventive and curative health measures, which guarantee the highest possible level of health. The petitioners' concern that compulsory vaccination abuses children is thus unfounded.

24. Regarding the petitioners' concern that the challenged ZNB provisions were contrary also to the provisions of Art. 47 of ZZDej and Art. 47 of ZZdrS, which contain the principle of conscious consent of a patient to a medical intervention as the basic principle of modern medicine ethics, it is necessary to explain that the Constitutional Court has no jurisdiction to decide on the mutual consistency of statutes or statutory norms, except when due to their mutual inconsistency the principles of a state governed by the rule of law (Art. 2 of the Constitution) are violated. This case is not such an example. Even if a medical intervention is made without consent, as in the case of compulsory vaccination, the physician must explain the patient (when the patient is a child, their parents or custodians) the intention, effects, and side effects of the intervention. The petitioners' assertions relating to the activities of physicians in concrete cases, however, cannot be a basis for the constitutional review of the challenged provisions.

25. The petitioners also pointed to the incompatibility of interests and the inappropriateness of procedures for the approval of vaccines, the formation of recommendations for vaccination, and the import of vaccines. In this respect it is necessary to emphasize that Art. 5.3 of ZNB determines the tasks of the IVZ in the area of protection against infectious diseases. According to the mentioned statutory provision, the IVZ and regional institutes observe and study epidemiological conditions of infectious diseases, in conformity with the obligations assumed with international agreements and the programs of WHO, and on such bases and in conformity with the plan of health care of the Republic of Slovenia prepare programs for the prevention, control, elimination, and eradication of infectious diseases. These programs are determined by the Minister of Health, for a particular year or a longer period. The program must determine measures, their implementers, time limits for the performance of individual tasks, and

necessary financial resources (Art. 5.4 of ZNB). Thus, the yearly program of vaccination and protection by medicines, and the conditions and manners of the implementation of this program, are determined by the Minister of Health, on the proposal of the IVZ (Art. 25.1 of ZNB). In the program of immunoprophylaxis and chemoprophylaxis for an individual year also the performers of the program are always determined. One of them is the IVZ. The conditions and procedure for obtaining a special permit for the import of medicines (among such also vaccines), which is issued by the Office of the Republic of Slovenia for Medicines, are determined by the Rules on Conditions and Procedure for Obtaining a Special Permit for the Import of Medicines and Medical Instruments (Official Gazette RS, 72/2000). As for all other medicines, the IVZ must obtain an appropriate permit by the Office of the Republic of Slovenia for Medicines also for the import of vaccines. The Medicines and Medical Instruments Act (Official Gazette RS, No. 101/99 et seq. – ZZMP) determines the conditions under which medicines can be put on the market. However, a concrete carrying out of these procedures cannot be a subject of constitutional review.

B. – III.

26. The allegation of the petitioners that the legislature did not regulate the rights of injured persons or proceedings in which they could protect their rights is substantiated. Art. 22.2 of ZNB determines that a physician performing vaccination must determine in advance whether there are well-founded reasons for refraining from vaccination (contraindications), whereas an expert commission appointed by the minister responsible for health shall decide whether there are permanent well-founded reasons for refraining from vaccination (permanent contraindications) (Art. 22.3 of ZNB). Applying a linguistic interpretation of the above-cited statutory provision, it could be concluded that the expert commission "decide" whether there exist permanent well-founded reasons for refraining from vaccination. However, the practice has not developed in this direction. The expert commission is namely functioning only as an advisory body and gives opinions whether there exist (permanent) contraindications in cases in which a physician performing vaccination requests such an opinion. Thus, the expert commission does not issue decisions by which it would decide on the rights and obligations. Furthermore, it does not follow from legislative materials whether the intention of the legislature was that the expert commission issued any decisions. As regards the fact that the legislature did not regulate special proceedings, the expert commission could proceed applying the provisions of administrative procedure, for which basis is provided in Art. 4 of the General Administrative Procedure Act (Official Gazette RS, No. 80/99 et sub. – hereinafter ZUP). However, the statutory regulation regarding the above-mentioned issue is not clear. Moreover, the legislature did not define the rights of individuals (or parents or other statutory representatives of a child) in proceedings for determining contraindications. ZNB namely does not determine by which legal remedies, in which proceedings, and before which body, an individual may pursue their disagreement with the physician's decision regarding the (non)existence of well-founded reasons for refraining from vaccination (contraindications), or their disagreement with the expert commission's decision regarding the (non)existence of permanent well-founded reasons for refraining from vaccination (permanent contraindications). The expert commission issues an opinion on the (non)existence of contraindications upon the proposal of a physician performing vaccination. The opinion is in general sent only to the physician performing vaccination, and not also to the

parents. In cases in which parents are (still) opposed to vaccination of their child, a physician is obliged to inform the Health Inspectorate of the Republic of Slovenia (hereinafter Inspectorate). The latter issues a decision by which it orders the parents that they are obliged to bring their child for vaccination. Against the decision of the Inspectorate an appeal to the ministry responsible for health is allowed. Moreover, against the minister's decision a judicial review of administrative acts is allowed. The Inspectorate simultaneously motion for the commencement of the minor offence proceedings pursuant to Art. 57 of ZNB. Hence, the parents are provided the position of parties to proceedings not until inspection proceedings (and later in minor offence proceedings). As regards the fact that compulsory vaccination is an interference with the constitutional rights of individuals, the legislature should separately regulate also the proceedings for establishing contraindications (either administrative or other), within the scope of which injured parties would have the opportunity to pursue their rights. In cases of compulsory vaccination of children, the legislature should furthermore determine the position of parents or guardians in such proceedings, and the position of a child of a sound mind. Pursuant to the present statutory regulation, injured parties are guaranteed judicial protection against decisions of an inspectorate body or against decision on a minor offence, however, according to the Constitutional Court this does not suffices. In accordance with Art. 23.1 of the Constitution everyone has the right to have any decision regarding his rights and duties made by a court. In the present case, judicial protection can be effective only if it is guaranteed already at the stage of deciding on the (non)existence of well-founded reasons for temporary or permanent refraining from vaccination. Due to the fact that the Act does not regulate the proceedings for pursuing the rights of individuals regarding establishing well-founded reasons for refraining from vaccination and regarding such it does not guarantee the right to judicial protection, it is inconsistent with Art. 23.1 of the Constitution.

27. The allegation of the complainants that ZNB did not regulate the rights of injured persons, as it can be interpreted that the legislature did not regulate the liability for damage which could arise due to side effects of vaccination is also substantiated. In order to protect the health of the community, the legislature placed an interest of the community before an interest of an individual, as it interfered with physical integrity of an individual, with their right to decide on themselves, and with the principle of a voluntary health treatment. A general interest for the protection of the health of the population is thus the basis which substantiates the measure of compulsory vaccination against certain communicable diseases. As any medical intervention also vaccination entails certain risks. An individual medical measure may certainly be determined only by assuming that in general it does not cause negative effects for the health or lives of people which are subjected to it (apart from temporary and milder effects which are part of any routine medical intervention and are therefore acceptable). However, if damaging side effects still occur, the legislature is obliged to ensure injured persons an appropriate protection in a form of a compensation for damage.¹³ It follows from the reasoning of the ZNB draft that the general rules on the liability for damage should be applied for possible damage claims in cases in which damage to the health of individuals was incurred due

¹³ In most countries (even where vaccination is only recommended) protection through the compensation of persons who suffer harmful consequences to their health due to vaccination is provided (in England for example the protection through compensation is regulated by a special act known as "Vaccine Damage Paying Scheme"). The standpoint that when an individual suffers harmful consequences due to compulsory vaccination they must be acknowledged the right to compensation was also taken by the Constitutional Court of Italy, in Decision No. 307 reached in 1990 and in Decision No. 118 reached in 1996.

to compulsory vaccination. However, the Constitutional Court assesses that the legislature should separately regulate the protection of injured persons in a form of a compensation for damage. The principle of solidarity which is *inter alia* a basis for determining a measure of a compulsory vaccination namely requires that the state which ordered such measure to the benefit of everyone, compensates injured individuals for damage that was incurred due to such measure, irrespective of the existence of the presumptions of the liability for damage pursuant to the general rules.¹⁴ It would be inadmissible if an individual alone endured damage which was incurred due to compulsory medial measure determined for the general benefit. The legislature is thus obliged to explicitly regulate protection in a form of a compensation for damage for such cases.

28. ZNB is inconsistent with the Constitution (the second paragraph of the present disposition), as it does not regulate proceedings and the rights of injured persons regarding establishing well-founded reasons for refraining from compulsory vaccination, or the protection in a form of a compensation for damage for persons that incurred damaging effects to their health due to compulsory vaccination. As it is the case in which the legislature did not regulate certain issues which it should regulate, an annulment is not possible. Therefore, pursuant to Art. 48 of ZUstS, the Constitutional Court adopted a declaratory decision. One year is in the opinion of the Constitutional Court an appropriate time limit for the legislature to abrogate the established inconsistency with the Constitution considering the reasons of the present decision.

C.

29. The Constitutional Court reached this decision on the basis of Arts. 21 and 48 of ZUstS, composed of: Dr. Dragica Wedam-Lukić, President, and Judges: Dr. Janez Čebulj, Dr. Zvonko Fišer, Lojze Janko, Marija Krisper Kramberger, LL.M., Milojka Modrijan, Dr. Ciril Ribičič, and Jože Tratnik. The first paragraph of the disposition was reached by seven votes against one. Judges Čebulj voted against. The second and third paragraphs of the disposition were reached unanimously.

Dr. Dragica Wedam-Lukić
President

¹⁴ For example Judgement of the Supreme Court of SR Slovenia No. Pž 324/77, dated 19. 5. 1977, published in Poročilo sodne prakse VS SR Slovenije [Report on the Case Law of the Supreme Court of SR Slovenia] No. II/1977, p. 31, indent 9. It should be emphasized that the Act on Protection of Population from Infectious Diseases (Official Gazette SRS, No. 7/77), which was then in force, regulated in Art. 30 the compensation of damage caused by vaccination, namely it determined the following: "If by compulsory immunization, seroprophylaxis or chemoprophylaxis against infectious diseases damage was caused to the health of a person, which can not be attributed to professional incorrectness in the manner of or through the procedure for immunization, the socio-political community, whose authority ordered the immunization, shall be held responsible for the damage caused." A substantially equal provision was preserved in the Act on the Protection of Population against Infectious Diseases of 1987 (Official Gazette SRS, No. 18/87). Compare also judgment of the Supreme Court of Bosnia and Herzegovina No. Gž 819/78, dated 22. 9. 1978, published in Bilten Vrhovnog suda BiH [The Bulletin of the Supreme Court of BiH] No. 4/78, p. 28.