

Pl. ÚS 19/14 of 27 January 2015
Compulsory Vaccination

CZECH REPUBLIC
CONSTITUTIONAL COURT
JUDGMENT

IN THE NAME OF THE REPUBLIC

HEADNOTES

With the help of linguistic and systematic interpretation, it might be justifiably concluded that the text of Section 46 of the Public Health Protection Act is sufficiently clear and comprehensible and reliably imply basic attributes and limits of the legal regulation of the compulsory vaccination against infectious diseases. The authorisation which is provided to the Implementing Decree to regulate the details associated with the performance of compulsory vaccination is applied by the secondary regulation within the given limits without interfering with the elements contained in the substantial features of law. Therefore, there has been no legislative interference with the guarantees provided to the holders of fundamental rights and freedoms under Article 4 (1) and (2) of the Charter.

Comparing the interest in the protection of public health and the fundamental rights and freedoms that are or may be affected by the compulsory vaccination against infectious diseases is a polyvalent matter also because the fundamental rights also include human, civil, and social rights. The Constitutional Court hereby makes in relation to Section 46 of the Public Health Protection Act the annulment of which the complainants have sought general conclusions concerning its compliance with the principles of the Constitution and the Charter, without interfering with expert or political spheres. The public interest in relation to the fundamental rights may be assessed at the level of constitutional review of the legal regulation of compulsory vaccination in terms of necessity. The review applies to the general statutory guarantees of the procedures of compulsory vaccination, while the determination of detailed rules of compulsory vaccination, based on expert knowledge, must be, even bearing in mind their impact on the circumstances of an individual, left to the executive field and the conceptual considerations of legislative policy.

The current legal regulation of the issue of compulsory vaccination against infectious diseases allows responding to the development of the incidence of individual infectious diseases in any country sufficiently quickly, as well as responding to the state-of-the-art knowledge in the fields of medicine and pharmacology. This is reflected in amendments to Decree No. 537/2006 Coll., on the vaccination against infectious diseases (No. 65/2009 Coll., No. 443/2009 Coll., and No. 299/2010 Coll.), and the previously valid Decree No. 439/2000 Coll., concerning the same issue, which have amended the extent of compulsory vaccination.

The Constitutional Court considers it desirable to express an opinion on the subject of its review also *obiter dictum*. Its positive conclusions on the fulfilment of *reservatio legis* and the necessity of the legal regulation of compulsory vaccination have exhausted the scope of the review and have not entitled the court to assess the complainants' objections (in fact, formulated *de lege ferenda*) to the absence of the legal regulation of the state's liability for damage caused to individuals by vaccination. If, however, the state provides for a penalty in the event of the refusal to submit to the obligation to undergo vaccination, it must also consider the situation where the vaccinated person suffers an injury to health as a result of the enforcement of law by the state. The space required to compensate such person is reopened by the Convention on Biomedicine which is part of the constitutional order and, in Article 24, mentions "fair compensation" for "inadequate injury" to health caused by any medical procedure as provided by law. Part of the consideration concerning the compensation may also be the legal regulation of material and non-material damage under the Civil Code. However, the fact that the compulsory vaccination is a medical procedure of a preventive nature, done in the interests of public health, approbated by law, and having an extraordinarily wide personal range and impact, cannot be ignored. These circumstances make it difficult for the legal position of a person who may sustain an injury to health as a result of vaccination and it is therefore necessary that the legislature should consider an amendment to the legal regulation of the institution of compulsory vaccination against infectious diseases by the regulation of the state's liability for the consequences mentioned above. It should occur even more so when such legal regulation is not exceptional whatsoever in other states (cf. the appropriate objection addressed in this respect to the

legislature by the Constitutional Court of Slovenia in the decision of 12 February 2004, file No. U-I-127/01).

VERDICT

The Constitutional Court has decided through the plenum composed of its President of the Constitutional Court Pavel Rychetský and judges Ludvík David (judge-rapporteur), Jaroslav Fenyk, Jan Filip, Vlasta Formánková, Vladimír Kůrka, Tomáš Lichovník, Jan Musil, Vladimír Sládeček, Radovan Suchánek, Kateřina Šimáčková, Vojtěch Šimíček, Milada Tomková, David Uhlíř, and Jiří Zemánek on the petition filed by the complainants: (1) L. C., (2) A. C., and (3) minor A. C., represented by Mgr. David Zahumenský, lawyer, based at Burešova 6, Brno, seeking the annulment of Section 46 of Act No. 258/2000 Coll., on the public health protection, as amended, and Section 29 (1) (f) of Act No. 200/1990 Coll. adopted by the Czech National Council, on administrative offences, as amended, with the participation of the Chamber of Deputies of the Parliament of the Czech Republic and the Senate of the Parliament of the Czech Republic as parties to the proceedings, as follows:

The petition seeking the annulment of Section 46 of Act No. 258/2000 Coll., on the public health protection, as amended, and the annulment of Section 29 (1) (f) of Act No. 200/1990 Coll. adopted by the Czech National Council, on administrative offences, as amended, is dismissed.

REASONING

I.

Subject of proceedings

1. In the proceedings concerning the constitutional complaint conducted under file No. I. ÚS 1253/14, the complainants L. C., A. C., and minor A. C. (represented by her parents who authorised a lawyer to represent her in the proceedings concerning the constitutional complaint and the petition seeking the annulment of both statutory provisions) sought the annulment of the judgment of the Supreme Administrative Court of 17 January 2014, ref. No. 4 As 2/2013-75, and the judgment of the Municipal Court in Prague, of 31 October 2012, ref. No. 4 A 43/2012-118. They held that ordinary court had infringed through the mentioned judgments upon their fundamental rights guaranteed under Article 2 (3) of the Constitution of the Czech Republic (hereinafter referred to as the “Constitution”), Article 9 of the Convention for the Protection of Human Rights and Fundamental Freedoms (hereinafter referred to as the “Convention”), and Article 2 (2) and (3), Article 3 (3), Article 4, Article 7, Article 10, Article 11, Article 15, Article 31, and Article 32 (4) of the Charter of Fundamental Rights and Freedoms (hereinafter referred to as the “Charter”). Along with the constitutional complaint in which the complainants rallied against the fines imposed on the parents in administrative proceedings due to their rejection of routine vaccinations of the minor, the complainants has filed, because of the alleged interference with the cited fundamental rights and freedoms, the petition seeking the annulment of Section 46 of Act No. 258/2000 Coll., on the public health protection, as amended (hereinafter also referred to as the “Public Health Protection Act”), and the provisions of Section 29 (1) (f) of Act No. 200/1990 Coll. adopted by the Czech National Council, on administrative offences, as amended (hereinafter also referred to as the “Act on Administrative Offences”).

2. I. The Panel of the Constitutional Court, after finding that the petitioners are as persons entitled to file a constitutional complaint legally represented (Section 30 (1) of Act No. 182/1993 Coll., on the Constitutional Court, as amended; hereinafter referred to as the “Act on the Constitutional Court”) and that their timely filed petition complies with the prescribed statutory requirements (Section 34 (1) of the Constitutional Court), decided on 11 September 2014 through a resolution under Section 78 (1) of the Act on the Constitutional Court to suspend the proceedings in the case of the constitutional complaint of the complainants against the above-indicated judgments of ordinary courts and to refer the complainant’s petition seeking the annulment of the parts of the legal provisions as indicated by the complainants to the Plenum of the Constitutional Court which discussed the matter and decided it under file No. Pl. ÚS 19/14.

II.

Recapitulation of the petition

3. In their petition seeking the annulment of the above-cited legal provisions, the complainants objected primarily to the conflict of the legal regulation of compulsory vaccination with Article 4 of the Charter. They argued that the Constitutional Court had repeatedly stressed in its case-law relating to health care that the limits of fundamental rights and freedoms might only be regulated by law subject to the conditions laid down in the Charter. Most recently this has been dealt with in the judgment file No. Pl. ÚS 43/13 concerning the spa treatment or the judgment file No. Pl. ÚS 36/11 concerning the above-standard health care. The complainants also pointed to the judgment of the Constitutional Court of the Slovak Republic file No. Pl. ÚS 8/94, dealing

with the *reservatio legis* regarding the decree of the Slovak Ministry of Health on the conditions of compulsory vaccination.

4. The complainants agree with the legal opinion of the panel of the Supreme Administrative Court which concluded under file No. 3 Ads 42/2010 that the legal regulation of compulsory vaccination in force in the Czech Republic is unconstitutional due to its conflict with Article 4 of the Charter. The Supreme Administrative Court holds that the rule guaranteeing the imposition of obligations solely on the basis of law and within its limit and only while maintaining the fundamental rights and freedoms has been infringed upon. The complainants have also referred to the dissenting opinion of three judges of the Supreme Administrative Court on the resolution of the extended panel of the same court, file No. 7 As 88/2011, of 23 April 2013. They agree with their legal opinion that the extended panel has failed to assess as for the compulsory vaccination of children to the necessary extent the matter of the interference of vaccination with the fundamental human rights, especially the right to bodily integrity and the right to family and private life. In order to be in compliance with the purpose of the protection of public health, any interference with those rights must respect the guarantees given to individuals by the Charter. It was implied then for the case under consideration that the obligations associated with the compulsory vaccination and limiting the fundamental rights had to be established by law.

5. In their submission, the complainants cited the case-law of the Constitutional Court concerning Article 4 of the Charter on *reservatio legis*. In its judgment file No. Pl. ÚS 35/95, the Constitutional Court states that citizens are entitled to free health care and medical aids based on the public health insurance and under the terms and conditions further defined by law. If the conditions may only be regulated by law, then it is imperative that the scope and manner of their fulfilment should be determined in the identical legislative regime. Other than regulation through law would constitute a violation of the Charter. The Constitutional Court, moreover, states in the judgment that it is not possible to allow the definition of the extent of health care provided for full or partial reimbursement otherwise than through statutory regulations. Otherwise, this area of the protection of fundamental rights and freedoms would fall under the competence of the executive power which, however, lacks the proper authorisation for that.

6. Another relevant ruling in relation to the alleged violation of Article 4 of the Charter indicated by the complainant is the judgment of the Constitutional Court file No. Pl. ÚS 45/2000. It is stated therein that individuals are protected against excesses of the executive power by the barrier of matters reserved to be regulated only through laws (i.e. *reservatio legis*). The complainants concluded that even in the case of compulsory vaccination it is necessary to insist on the application of *reservatio legis*. The reason is to prevent the excesses of the executive power, which is required according to the complainants clearly due to the lack of transparency and inadequacy of the extent of compulsory vaccination against the interest of minors. If the Ministry of Health has so far regulated the institution of compulsory vaccination only by a decree as secondary legislation, the defence against such departure through a reference to *reservatio legis* is completely justified. The complainants believe that defining the scope of the obligation to be vaccinated cannot be left to other than legal regulations. In view of the complainants, the scope of limitations of fundamental rights falling into the realm of law under Article 4 of the Charter must be modified at least within the provisions specifying the diseases subject to vaccination and the time limits within which a person is obliged to undergo the vaccination.

7. The complainants stresses that the legal regulation of the compulsory vaccination against infectious diseases appears to be in conflict with Articles 5, 6, and 26 of the Convention for the Protection of Human Rights and Dignity of the Human Being, with regard to the Application of Biology and Medicine (also Convention on Human Rights and Biomedicine, promulgated under no. 96/2001 of the Collection of International Treaties, hereinafter referred to as the “Convention on Biomedicine”), since it violates the limits of the limitation of the enforcement of law in relation to the required need for the consent of the obliged person to any medical procedure. As the compulsory vaccination does not comply with the condition that it must be a measure necessary in a democratic society. The condition that it is a limitation in the interest of the protection of public health is not complied with in the case of tetanus vaccination either.

8. In order to assess the necessity of a measure in a democratic society, it is necessary to perform a proportionality test or necessity test. The necessity means that in order to protect a certain social interest it is not possible to use any more considerate means. The necessity requirement has an objective nature. For example, in all countries, in order to protect the public health, it is necessary to isolate a patient with a serious infectious disease that can be communicated to others. The very fact that a certain measure is taken in all democratic countries is a sign of necessity. But if countries with the same or a comparable epidemiological situation, such as Germany or Austria, do not require the compulsory vaccination of children, it is hard to defend such “necessity” in the Czech Republic. An attribute of a necessary measure is also its enforceable nature. The limitation of the

exercise of individual rights in favour of the public interest necessitates the possibility of an interference conducted even against the will of the persons concerned. Within the legal regulation of compulsory vaccination in the Czech Republic, however, the enforceability is missing, thereby significantly challenging the necessity of this institution. The obligation to undergo vaccination is not acceptable for the lack of objective substrate in the form of an independent and comprehensive analysis that would show the medical necessity and undesirable consequences of the vaccination measure.

9. The complainants have further raised an objection concerning the conflict of compulsory vaccination with the constitutionally guaranteed rights as set out in Article 10 (1) and (2) and Article 15 (1) of the Charter. They state that they decided not to have their minor daughter vaccinated because they believed it was in the best interest of the protection of health of their child. The legal regulation of the compulsory vaccination applied in administrative proceedings constitutes in view of the complainants an unconstitutional interference with the right to human dignity, the right to privacy, and the freedom of thought and conscience. The legal arguments of the complainants are based on the judgment of the Constitutional Court file No. III. ÚS 449/06, from which they conclude that in exceptional cases where the vaccination of a child is contrary to the thought and conscience of parents the parents cannot be penalised for failure to have their children vaccinated. They assumed that they fulfilled all the criteria so that the exception could be granted in their case and that they should not be penalised in administrative proceedings with respect to the absence of a substantive aspect of the administrative offence. Yet they were penalised and their administrative action was dismissed without the impact of the legal opinion of the Constitutional Court on their case being adequately dealt with by the courts.

10. The complainant inferred from the mentioned judgment file No. III. ÚS 449/06 an argument that the public authorities must not enforce compulsory vaccination if circumstances exist that fundamentally call for maintaining the autonomy of the will of the person concerned and for imposing no penalties for any violation of the obligation to undergo vaccination in extraordinary circumstances. Any administrative review must take into account all the relevant factors, particularly the constitutional intensity and urgency of arguments against the obligation to undergo vaccination, as well as any possible danger to the society, which may be brought about by the attitude of the person violating the obligation to undergo vaccination. However, any social dangerousness of the considered act has not been demonstrated in any manner whatsoever in the administrative proceedings conducted against them.

11. The complainants pointed out that the attitude of parents to the vaccination of their children is always an expression of their inner beliefs and constitutionally guaranteed rights. It is not possible to assess objectively which approach to vaccination is reasonably in favour of a child or in the interest of the protection of public health. The opinions of physicians and other experts at vaccination and its required extent, including the evaluation of the effectiveness, usefulness or harmfulness of vaccines, also differ. There are no relevant studies comparing the long-term state of health of vaccinated and unvaccinated individuals. Nor is it possible to assess clearly the extent to which the vaccination contributed in the past to the elimination or reduction of infectious diseases and the extent to which it is the result of hygiene and improving living standards of the population. The attitude of each person to vaccination is based on her personal relationship to the problem, rather than on the objective data. It is therefore inconceivable for the administrative authority to examine the “correctness” or “reasonableness” of the belief of parents on the inappropriateness of the vaccination of their child. Such review would demonstrate an impermissible interference of state authorities with the private sphere of natural persons.

12. The beliefs of parents do not always outweigh other interests understandably. Therefore, for instance, it is permissible to treat a child against the will of the parents in order to save the life or preserve the health of the child or to impose quarantine on a person with a serious infectious disease. However, in the case of routine (not emergency) vaccination of a healthy person, any other interest may by definition prevail over the respect to the freedom of thought and conscience of parents and the bodily integrity of the minor child.

13. The repeated objection of complainants has been directed to the conflict of the legal regulation of compulsory vaccination with the fundamental rights to the inviolability of person, privacy, and health within the meaning of Article 7 (1) and Article 31 of the Charter. In addition, Article 24 of the Convention on Biomedicine lays down the right to compensation for damage caused by any medical operation: “A person who has suffered inadequate damage due to a medical operation is entitled to fair compensation according to the conditions and procedures prescribed by law.” However, this postulate is not consistent with the situation in which the vaccination is required by the state as compulsory, but the same state at the same time has not assume any liability for any possible side effects and damage to health caused by the vaccination. Any negative effects of vaccination, including costs incurred for the treatment of injury, only affect the persons concerned. The described legal status is in the opinion of the complainants contrary to the requirement of the European Court of

Human Rights (hereinafter referred to as the “ECHR”) for a fair balance between the public interest and the rights of individuals.

14. The complainants therefore rallied against the contested legal regulation in several ways. Above all, they criticised the absence of regulation of the scope and manner of compulsory vaccination in law, although this regulation directly affects the fundamental rights and freedoms of vaccinated individuals and their parents. In their view, the vaccination against infectious diseases should not be compulsory, especially given the epidemiological situation in the Czech Republic and comparable conditions in other European countries. At the same time, the complainants argue that the administrative authorities and administrative courts when imposing a penalty did not take into account the particular circumstances of the case, namely due to the reasons for which they did not provide the cooperation necessary for the vaccination of their minor child. Finally, they believe that natural persons should be entitled to fair compensation within the protection against the adverse effects of vaccination if they suffer as a result of vaccination any substantial injury to health.

III.

Statements of the parties to the proceedings

15. In its statement received by the Constitutional Court on 24 October 2014, the Chamber of Deputies of the Parliament of the Czech Republic merely described the course of the legislative process leading to the adoption of laws whose provisions are covered by the petition. It stated that the bills were agreed in a constitutionally prescribed procedure by both chambers of the Parliament of the Czech Republic and the acts were signed by the appropriate constitutional officials and duly promulgated. Finally, Chamber of Deputies expressed that it is for the Constitutional Court to examine the question of the alleged unconstitutionality of the contested statutory provisions and rule on the petition seeking the annulment thereof.

16. The statement of the Senate of the Parliament of the Czech Republic was delivered to the Constitutional Court on 23 October 2014. After summarising the important contents of the constitutional complaint, the Senate commented on individual contested provisions of the Public Health Protection Act and the Act on Administrative Offences. In both cases, the Senate did so with an emphasis on the procedure of passing the bill; as for Section 46 of the Public Health Protection Act, the Senate also cited part of the explanatory memorandum as to the original version of the Government bill, as well as some parts of the debate in the Senate. The Senate concluded that its statement was submitted with the knowledge that it is fully for the Constitutional Court to assess the petition seeking the annulment of contested statutory provisions and to rule on the case.

17. The Government of the Czech Republic notified on 27 October 2014 that it did intend to use its right to intervene in the proceedings pursuant to Section 69 (2) of the Act on the Constitutional Court, as it held that its participation in the proceedings was not necessary. The Government stated that the Constitutional Court dealt in detail with the objection of unconstitutionality of the penalty for failure to undergo the compulsory vaccination and the issue of the constitutionality of the statutory obligation to undergo routine vaccinations addressed in its judgment, file No. III. ÚS 449/06, of 3 February 2011. The conclusions of the identified decisions were repeatedly approved by the Constitutional Court (see e.g. resolution file No. I. ÚS 409/14, resolution file No. III. ÚS 271/12, and resolution file No. II. ÚS 271/12) and the Government fully agrees with them.

18. The Government’s notice subsequently refers to its observations on the matter of legitimacy and rationality of the statutory obligation to undergo routine vaccinations, respectively the legitimacy of the objective pursued by the legal regulation of compulsory vaccination against infectious diseases (protection of public health). This statement has been sent by the Government as to the petition being subject to the proceedings conducted by the Constitutional Court, file No. Pl. ÚS 16/14, in the case of review of the constitutionality of Section 50 of the Public Health Protection Act and Section 34 (5) of Act No. 561/2004 Coll., on preschool, primary, secondary, vocational, and other education (Education Act), as amended.

19. The Public Defender of Rights notified the Constitutional Court of her decision not to intervene in the proceedings. However, she attached a text identifying her therein as *amicus curiae* and expressing her conviction of the necessity to review the system of compulsory vaccination against infectious diseases in the Czech Republic, although she did not contest the system itself. She summed up the experience of the Office of the Public Defender of Rights, according to which complainants most often criticise the scope of compulsory blanket vaccination, vaccination side effects, lack of awareness among parents, and some practical problems (such as failure of the public health insurance system to pay some vaccines). The Public Defender of Rights has also been notified of some risks of the current vaccination system by some neurologists and allergists. She has repeatedly pointed in the summary reports of its activities to the need for an individualised approach in the

application of the Public Health Protection Act; the current legal regulation provides only minimal space for exceptions and sets serious penalties. Already in 2004, the then Public Defender of Rights applied to the Ministry of Health to deal with possible exceptions from the compulsory vaccination and consider the possibility of amending the legal regulation. Being aware of the risk of the rejection of an objective debate and the opposition of the legislature towards any changes, the Public Defender of Rights noted that the possible annulment of Section 46 of the Public Health Protection Act would not necessarily call into question the system of compulsory vaccination in the Czech Republic. On the contrary, it could open the much-needed space for its revision based on the serious professional debate on the desirability of the current scope of compulsory blanket vaccination of children as compared to the risks of non-vaccination for individuals and for the society (taking into account the possible adverse effects of vaccination). The much-needed confidence in the chosen system of vaccination may also be enhanced by a more sensitive individual approach, “loosening” of vaccination schedule, and payment for more effective vaccines from the public health insurance system.

IV.

Conditions of the *locus standi* of the petitioners

20. The complainants proposed the annulment of the cited statutory provisions, together with a constitutional complaint filed pursuant to Section 72 (1) (a) of the Act on the Constitutional Court. Their *locus standi* to submit an accessory petition for a specific review of regulations is based on Section 64 (1) (e) in connection with Section 74 of the Act on the Constitutional Court. The Constitutional Court must first examine whether the conditions for the submission of such petition are complied with on the part of the complainants.

21. A condition for submitting a petition under Section 74 of the Act on the Constitutional Court is the “application” of the contested legal regulation. It means that the application of the concerned regulation has resulted in any legal circumstance (a decision, a measure or any other interference by a public authority) subject to a constitutional complaint and having negative effects in a legal sphere of the complainant, i.e. there was an alleged infringement upon the complainant’s constitutionally guaranteed fundamental rights and freedoms. There must be a close relation between a decision, a measure or any other interference by a public authority and a legal regulation (its provision) contested by the constitutional complaint and proposed to be annulled in the sense that if it were not for the contested legal regulation a legal act of a public authority would not have occurred as a result of that.

22. The petition seeking the annulment of Section 46 of the Public Health Protection Act and Section 29 (1) (f) of the Act on Administrative Offences due to their conflict with the enumerated provisions of the Convention, the Constitution, and the Charter was filed by the complainants together with a constitutional complaint under file No. I. ÚS 1253/14. The factual basis of the constitutional complaint was their opposition to being obliged to ensure that their child should undergo specified routine vaccinations. They rallied against the decision to impose an administrative penalty (fine) due to the lack of cooperation (failure to respect the vaccination schedule resulting in the absence of vaccination) with a health care provider. The competent public health station imposed upon each of them a penalty of CZK 6,000 on 7 July 2009, which was decreased upon their appeal through a decision by the Ministry of Health of 13 August 2009 to CZK 4,000 for each of them. The complainants filed an administrative action which was complied with at first by a judgment of the Municipal Court in Prague of 27 August 2010, ref. No. 4 Ca 26/2009-56, annulling the decision of the Ministry, but then the Ministry filed a cassation complaint against the judgment and the Supreme Administrative Court through its judgment, ref. No. 4 As 8/2011-98, of 29 May 2012 annulled the judgment of the Municipal Court in Prague the case was referred back for reconsideration and a new decision. It was followed by a new judgment of the Municipal Court in Prague, ref. No. 4 A 43/2012-118, of 31 October 2012, dismissing the complainants’ action. After the cassation complaint was filed by the complainants, the Supreme Administrative Court dismissed the complaint through its judgment, ref. No. 4 As 2/2013-75, of 17 January 2014; the judgment came into legal force on 4 February 2013.

23. The described facts that interfered with the legal sphere of the complainants in close connection with the required compulsory vaccination of their daughter (i.e. the third complainant) were based on the application of Section 46 of the Public Health Protection Act in connection with Decree No. 537/2006 Coll., on the vaccination against infectious diseases, as amended, issued by the Ministry of Health on 29 November 2006 (hereinafter referred to as the “Implementing Decree”), and the procedures in the implementation of compulsory vaccination regulated therein. The complainants contested Section 46 of the Public Health Protection Act for the failure to mention the full elements of the vaccination obligation under the act (see Item 14) and, in addition, concluded that if it were not for the legal regulation of the obligation to undergo vaccination against infectious diseases they would not have faced the administrative proceedings, any penalty would not have been imposed upon them, and their freedom of making decisions on the matters of their child (they did not have their daughter vaccinated,

according to their own claims, because of “their conscience and thought, ethical and philosophical beliefs, and their beliefs about the best interests of the minor to protect her health”) would not have been interfered with.

24. The conduct of the first two complainants motivated by the intention not to have their daughter (the third complainant) vaccinated was deemed to have fulfilled the facts of an administrative offence under Section 29 (1) (f) of the Act on Administrative Offences pursuant to which an administrative offence in the health care sector is committed by a person who violates a prohibition or fails to comply with an obligation as set out or imposed to prevent the incidence and spread of infectious diseases.

25. In relation to both legal provisions, the condition of filing a petition under Section 74 of the Act on the Constitutional Court has been complied with. Therefore, it was necessary to admit the locus standi of the complainant to file a petition and to subject their petition seeking the annulment of both statutory provisions to a constitutional review.

V.

Constitutional conformity of the legislative process

26. Pursuant to Section 68 (2) of the Act on the Constitutional Court, the Constitutional Court establishes whether an act has been passed and promulgated within the limits of constitutionally set powers and in a constitutionally prescribed manner.

27. Although, the petitioners did not object against any defect in the legislative procedure or exceeding the powers of legislature determined by the Constitution, the Constitutional Court nevertheless examined the course of the procedure of adopting the provisions at issue, based on the statements submitted to the Chamber of Deputies of the Parliament of the Czech Republic and the Senate of the Parliament of the Czech Republic, as well as publicly available information at <http://www.psp.cz>.

28. The valid and effective Section 46 of the Public Health Protection Act, which is proposed to be annulled, is including the original text also the result of amendments to Act No. 258/2000 Coll., on the protection of public health and amending some related acts, implemented by Act No. 274/2003 Coll., amending certain acts in the field of public health, Act No. 392/2005 Coll., amending Act No. 258/2000 Coll., on the protection of public health and amending some related acts, as amended, and some other acts, Act No. 41/2009 Coll., amending certain acts in connection with the adoption of the Criminal Code and Act No. 375/2011 Coll., amending some acts in connection with the adoption of the Health Services Act, Act on Specific Health Services, and the Emergency Medical Service Act.

29. The original bill of the Public Health Protection Act was submitted by the Government to the Chamber of Deputies on 10 February 2000 through the Document of the Chamber of Deputies No. 538/0. The first reading took place on 23 February 2000 and the bill was assigned to the Committee for Social Policy and Health Care. The Committee discussed the bill on 3 May 2000 and recommended that the Chamber of Deputies pass it in the wording of proposed amendments of the Committee. The second reading including a detailed debate took place on 18 May 2000 and the third reading took place on 25 May 2000. The Chamber of Deputies has given its consent to the bill as amended by the adopted proposed amendments, in voting No. 258, when out of 165 deputies present, 164 deputies voted in favour of the bill and none of deputies was against. The bill was referred to the Senate on 7 June 2000. The Senate returned it to the Chamber of Deputies with its proposed amendments. The bill returned by the Senate was discussed by the Chamber of Deputies on 14 June 2000 and was adopted by it in the wording approved by the Senate. In voting No. 699, out of 155 deputies present, 128 deputies voted for and 13 deputies voted against. Following the adoption of the Act and after it was signed by the competent constitutional officials, the act was promulgated in the Collection of Laws under No. 258/2000 Coll. on 11 August 2000.

30. The bill No. 274/2003 Coll., amending some acts in the field of public health, was submitted to the Chamber of Deputies by the Government through the Document of the Chamber of Deputies No. 215/0. The first reading took place on 9 April 2003 and the bill was assigned to the Committee for Social Policy and Health that discussed it on 5 June 2003. The bill was discussed by the Committee for European Integration on its own initiative on 13 June 2003. Both committees adopted proposed amendments to the bill, but without any effect on Section 46. The second reading of the bill took place on 3 July 2003 and the third reading on 8 July 2003. In voting No. 390, out of 177 deputies present, 127 deputies voted for the adoption of the act, 1 deputy was against. The bill was referred to the Senate on 14 July 2003, it was approved by the Senate on 7 August 2003, signed by the President on 20 August 2003, and promulgated in the Collection of Laws on 27 August 2003 under ref. No. 274/2003 Coll.

31. The bill No. 392/2005 Coll., on the protection of public health and amending some related acts, as amended, was submitted by the Government to the Chamber of Deputies as Parliament Document No. 824/0 on 16 November 2004. The first reading took place on 14 December 2004 and the bill was assigned to the Committee for Social Policy and Health Care that discussed it on 9 March 2005. Any proposed amendment to Section 46 of Act No. 258/2000 Coll. has been submitted neither at the Committee for Social Policy and Health Care nor in the second reading within the detailed debate. The third reading of the bill took place on 11 May 2005; in voting No. 98, out of 195 present deputies, 112 deputies voted for and 56 deputies votes against. On 23 May 2005, the bill was referred by the Chamber of Deputies to the Senate that rejected it on 17 June 2005. The bill rejected by the Senate was voted upon by the Chamber of Deputies on 19 August 2005, while in voting No. 84, out of 184 deputies present, 111 deputies voted for and 63 deputies voted against the bill. The President of the Czech Republic refused to sign the bill and returned it to the Chamber of Deputies on 12 September 2005. The bill returned by the Chamber of Deputies was voted upon by the Chamber of Deputies on 23 September 2005, while in voting No. 87, out of 166 deputies present, 107 deputies voted for and 51 deputies voted against the bill. The act was promulgated in the Collection of Laws under No. 392/2005 Coll. on 27 September 2005.

32. The bill No. 41/2009 Coll., amending certain acts in connection with the adoption of the Criminal Code, was discussed as the Government's bill in the Chamber of Deputies under No. 411/0. The Government's bill did not contain an amendment to Act No. 258/2000 Coll. The first reading of the bill took place on 14 March 2008 and the bill was assigned to the Committee for Constitutional and Legal Affairs and the deadline for discussing the bill in committees was extended for 20 days. The Committee for Constitutional and Legal Affairs discussed the bill on 19 June 2008. During the second reading within the detailed debate which took place on 31 October 2008, Deputy Radim Chytka proposed to complement the Government's bill by other regulations which should reflect a decrease in the age limit of criminal liability, including without limitation under Section 46 of Act No. 258/2000 Coll. In the third reading which took place on 11 November 2008, out of 139 deputies present, 107 deputies voted for and 25 deputies voted against the bill of Deputy Chytka in voting No. 46. The bill as a whole was voted upon in voting No. 51, and out of 140 deputies present, 116 deputies voted for and 2 deputies voted against. The Senate passed the bill on 8 January 2009, the President signed it on 27 January 2009, and it was promulgated in the Collection of Laws on 9 February 2009 under No. 41/2009 Coll.

33. The bill No. 375/2011 Coll., amending some acts in connection with the adoption of the Health Services Act, Act on Specific Health Services, and the Emergency Medical Service Act, was submitted to the Chamber of Deputies by the Government through Document of the Chamber of Deputies No. 408/0 on 30 June 2011. In the first reading of the bill held on 12 July 2011, the bill was assigned to the Committee for Health Care and, at the same time, the deadline for discussing the bill in committees was shortened for 20 days. The Committee for Health Care discussed the bill on 25 August 2011 and the bill was also discussed by the Committee for Defence and Security of its own initiative on 16 August 2011. The second reading of the bill took place on 30 August 2011. The summary of submitted proposed amendments was drawn up as Document of the Chamber of Deputies No. 408/3, while any proposed amendment did not concern the contested provision. In the third reading, the bill was discussed by the Chamber of Deputies on 7 September 2011 and was passed in voting No. 101; out of 158 deputies present, 92 deputies voted for the bill and 59 deputies voted against. The Senate discussed the bill on 12 October 2011 and rejected it. The bill rejected by the Senate was discussed by the Chamber of Deputies from 3 November to 6 November 2011. The Chamber of Deputies insisted on the original wording of the bill; in voting No. 343, out of 179 deputies present, 109 deputies voted for and 70 deputies voted against. The President of the Czech Republic signed the bill on 22 November 2011 and the act was published in the Collection of Laws on 8 December under No. 375/2011 Coll.

34. From the above recapitulation of the legislative procedure, it is clear that Section 46 of Act No. 258/2000 Coll. was adopted in a constitutionally prescribed manner.

35. The contested provision of Section 29 (1) (f) of the Act on Administrative Offences in the reviewed wording is a result of an amendment to the Act on Administrative Offences made in Section 113 (6) of the Act No. 258/2000 Coll., on the protection of public health and amending some related acts [previously, the contested provision was identified as (g)]. The legislative process was in this case flawless (see Item 29 of this judgment).

VI.

Waiver of hearing

36. When considering the petition, the Constitutional Court came to the conclusion that in this case an oral hearing does not need to be ordered as it would not bring any further clarification of the matter. Therefore,

according to the wording of Section 44 of the Act on the Constitutional Court, the Constitutional Court made its decision without holding a hearing.

VII.

Review background

37. The examination of the constitutionality of the act is based on the substantive and formal criteria applicable to the text. Based on the requirement for appropriate form, the law must promote the principle of legal certainty through its clarity and explicitness and its comprehensible and consistent wording must imply predictable consequences without any traces of arbitrariness on the part of the legislature [see the judgments of the Constitutional Court of 24 May 1994, file No. Pl. ÚS 16/93 (N 25/1 of the Collection of Judgments of the Constitutional Court 189), of 23 May 2000, file No. Pl. ÚS 24/99 (N 73/18 of the Collection of Judgments of the Constitutional Court 135), of 4 July 2000, file No. Pl. ÚS 7/2000 (N 106/19 of the Collection of Judgments of the Constitutional Court 45), of 12 February 2002, file No. Pl. ÚS 21/01 (N 14/25 of the Collection of Judgments of the Constitutional Court 97), and others]. The substantive criterion concentrates on the value aspect of the legal regulation. In the case under consideration, it is primarily expressed in the principles as set out in Article 2 (3) of the Constitution and Article 2 (2) of the Charter, and as elaborated upon under Article 4 (1) and (2) of the Charter, under which it is only permissible to exercise the state power within legal limits, obligations may only be imposed by law and within its limits, while maintaining the fundamental rights and freedoms, and the legal limits of the fundamental rights and freedoms must respect the conditions laid down in the Charter.

38. The Constitutional Court notes that the complainants failed to elaborate in their objections upon their claims that they acted according to their conscience and belief while not providing their cooperation necessary for the vaccination of their daughter (cf. the quote in Item 23 *in fine*). If they argue by merely referring to Article 15 of the Charter concerning the freedom of thought, conscience, and religion, as well as Article 9 of the Convention with similar content, then the Constitutional Court had no reason to deal with the subject-matter of their objections, especially when finding the core of the petition in the matters of compliance with *reservatio legis* and justification of the legal regulation of the compulsory vaccination.

39. The complainants' objection to an interference with Article 11 of the Charter concerning the protection of property was apparently motivated by the fact that they had been imposed a financial penalty for an administrative offence (to the detriment of their property), while this decision subsequently passed a review conducted by administrative courts. Answering this objection, however, was dependent on the decision of the Constitutional Court on the constitutionality of Section 29 (1) (f) of the Act on Administrative Offences, which is justified in the conclusions of the judgment rendered.

40. The common denominator of the complainants' objections based on the constitutional guarantees of the autonomy of the will of individuals and the ban on penalty imposed due to exercising fundamental rights and freedoms (Article 2 (3), Article 3 (3) of the Charter) is their close relationship to objections to the existence of the legal regulation of the compulsory vaccination and against the lack of legal regulation of compensation for an injury to health arising from the compulsory vaccination (see Item 14). The considerations dealing with any possible interference with the cited articles of the Charter were subject to the interpretation of the Constitutional Court of *reservatio legis* and the necessity for the legal regulation of compulsory vaccination, without giving a reason to separate them from the text. The issue of compensation for any injury to health is discussed in the conclusions of the judgment.

41. An obligation within the meaning of the list of fundamental rights and freedoms means a commitment of an individual towards the society the implementation of which may be required in the public interest, i.e. in the interest of specially protected values of the democratic rule of law. The determination of the obligation is subject to law, provided that a regulation of lower legal force which specifies the corresponding obligation must immediately conduct an initial prescriptive act and respect the limitations contained therein.

42. The law therefore imposes the primary obligations as may be elaborated upon in detail in the secondary legislation (Article 78, Article 79 (3), and Article 104 (3) of the Constitution). The secondary legislation must be *secundum et intra legem*. The legislature may not delegate the regulation of those obligations which form the actual content of the relevant legal regulation, define it, and determine its meaning and purpose [see the judgment of the Constitutional Court of 14 February 2001, file No. Pl. ÚS 45/2000 (N 30/21 of the Collection of Judgments of the Constitutional Court 261)], to the executive power.

43. The Constitutional Court stated in its judgment of 3 February 2011, file No. III. ÚS 449/06 (N 10/60 of the Collection of Judgments of the Constitutional Court 97) that the compulsory vaccination against infectious diseases is obviously a measure necessary in a democratic society for the protection of public safety, health, and the rights and freedoms of others. It also stated that the Convention on Biomedicine, which is according to the case-law of the Constitutional Court part of the constitutional order of the Czech Republic [cf. the judgment of 25 June 2002, file No. Pl. ÚS 36/01 (N 80/26 of the Collection of Judgments of the Constitutional Court 317; 403/2002 Coll.)], sets no authority whatsoever of the Constitutional Court to review the constitutionality or unconstitutionality of the actual legal obligation to undergo some kind of vaccination. Although the Convention on Biomedicine sets out the fundamental right not to be subject to any medical procedure without one's consent (Article 5 or for those unable to give their consent under Article 6) and admits, at the same time under Article 26, the limitations of such right if the limitations are prescribed by law and are necessary in a democratic society in the interests of public safety, protection against crime, public health protection or the protection of the rights and freedoms of others. The legislature's decision that a certain type of vaccination is compulsory is, therefore, according to the Constitutional Court, a decision which implements the option explicitly provided for in Article 26 of the Convention on Biomedicine. According to the Constitutional Court, "it is a decision which is primarily a political and expert matter and, therefore, there is a very limited possibility of interference by the Constitutional Court. Such decision of the legislature enjoys in relation to the Convention cited relatively large space for political discretion within which a decision of the legislature (or an implementing regulation of the executive power) establishing the obligation to undergo some kind of review of vaccination (margin of appreciation) cannot be reviewed. The Constitutional Court is the judicial body protecting the Constitution and its decision in principle cannot be replaced by the legislature or the executive power according to which certain infectious diseases require compulsory vaccination."

44. The ECHR interprets in its (still rather sporadic) case-law the matter of the relationship of compulsory vaccination against infectious diseases to human rights within the meaning of the Convention on Biomedicine. It respects in particular the structure of this Convention in which the said Article 26 constitutes an approbation of limitations necessary in a democratic society similar to those enumerated under Articles 8 to 11 of the (European) Convention in others "restrictive" paragraphs. The legal regulation of compulsory vaccination thus remains as interpreted by the Constitutional Court within the reference to Article 26 of the Convention on Biomedicine subject to the applicable national regulations.

45. These conclusions are confirmed by the judgment of the ECHR in the case of *Solomachin v Ukraine* of 15 March 2012, No. 24429/03, commenting on the aspects of the right to respect for privacy and family life under Article 8 of the Convention. The subject of the complaint was the decision-making by the Ukrainian judiciary concerning the injury to health caused to the complainant as a result of compulsory vaccination. The ECHR found that the bodily integrity of the person subject to the protection of private life according to the cited article of the Convention. Any medical procedure, even of low importance, constitutes an interference with the right to privacy, which limits an individual. The compulsory vaccination as a medical procedure forced upon an individual constitutes an interference with his/her bodily integrity. However, the procedure took place on the basis of law with the legitimate aim of protecting health. It was justifiable in the interests of public health with the need for the prevention of the spread of infectious diseases in the region.

46. Under Article 12 of the International Covenant on Economic, Social and Cultural Rights (No. 120/1976 Coll.), the Parties undertake to take measures, among other things, to ensure the healthy development of children and preventing, treating, and controlling epidemic diseases [paragraph (2) (a) and (c)]. European Social Charter (No. 14/2000 Coll. Ms) contains Article 11 called The right to protection of health which reads as follows: "With a view to ensuring the effective exercise of the right to protection of health, the Parties undertake, either directly or in cooperation with public or private organisations, to take appropriate measures designed *inter alia*: 1. to remove as far as possible the causes of ill-health; 2. to provide advisory and educational facilities for the promotion of health and the encouragement of individual responsibility in matters of health; and 3. to prevent as far as possible epidemic, endemic and other diseases, as well as accidents."

47. According to Article 35 of the Charter of Fundamental Rights of the European Union called Health care everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices. A high level of human health protection shall be ensured in the definition and implementation of all the Union's policies and activities The principles set forth herein are based on Article 168 (Public Health) of the Treaty on the Functioning of the European Union as amended by the Lisbon Treaty. The Court of Justice of the European Union, being asked by the Supreme Court of the Slovak Republic about the possibilities, limits, and effects of national regulation of compulsory vaccination in relation to EU legal acts, rejected through its resolution of 17 July 2014, under file No. C-459/13,

the preliminary matter raised as impermissible due to that the said matter is exclusively a matter of national legislations and judicial systems.

VIII.

The contested provisions and a summary of the Implementing Decree

48. The text of Section 46 of the Public Health Protection Act reads as follows:

Section 46

(1) A natural person who has his/her permanent place of residence in the territory of the Czech Republic, a foreigner who has been granted permanent residence, a foreigner who is entitled to permanent residence in the territory of the Czech Republic, and a foreigner who has been granted temporary residence in the territory of the Czech Republic for a period longer than 90 days or is entitled to permanent residence in the territory of the Czech Republic for a period longer than 90 days shall undergo the kind of routine vaccination in the cases and within the time limits as regulated in the implementing legislation. The natural persons named in the implementing legislation and the natural persons to be assigned to the workplace with an increased risk of infectious diseases are obliged to undergo the prescribed kind of extraordinary vaccination to the prescribed extent.

(2) Prior to carrying out routine and extraordinary vaccinations, in the cases specified in an implementation regulation, a natural person shall be obliged to undergo examination of the state of immunity (resistance). The routine and extraordinary vaccination shall not be carried out if the immunity against infection or if a health condition which prevents administering any vaccine (permanent contraindication) is established. The health care provider shall issue a document confirming such facts to the concerned natural person and shall enter the reason for abandoning vaccination in medical records.

(3) If the competent authority in charge of the protection of public health establishes that a minor natural person has failed to undergo vaccination or examination pursuant to paragraph 2 and it is a minor natural person who has not chosen a general practitioner, the authority shall impose upon that person through its decision the obligation to undergo vaccination or examination with the designated health care provider, as appropriate.

(4) As for a person under 15 years of age, his/her legal representative shall be responsible for the fulfilment of obligations pursuant to paragraphs 1 to 3.

(5) The authority in charge of the protection of public health that has issued a decision pursuant to paragraph 3 shall require the designated health care provider to perform such vaccination or examination. The designated health care provider shall comply with such request.

(6) The implementing legislation also regulates the classification of vaccination and the conditions of vaccination, the methods of examination of immunity, workplaces with a higher risk of acquiring infectious diseases, and the conditions under which natural persons may be assigned to work with a higher risk of acquiring infectious diseases in the context of extraordinary vaccination.

49. The relevant part of Section 29 (1) of the Act on Administrative Offences reads as follows:

Section 29

Administrative offences in the healthcare sector

An administrative offence is committed by a person who

(1)

(f) Violates a prohibition or fails to comply with an obligation laid down or imposed to prevent the emergence and spread of infectious diseases (...).

50. The implementing regulations (see the authorisation under Section 46 (1), (2), and (6) of the Public Health Protection Act) for the vaccination obligation is Decree No. 537/2006 Coll., on the vaccination against infectious diseases, as amended (hereinafter also referred to as the “Implementing Decree”). The decree states in the introductory provisions of Section 1 that its subject-matter is “(a) the classification of vaccination, conditions of vaccination and passive immunisation, methods of immunity investigation, workplaces with a higher risk of acquiring infectious diseases, and conditions under which natural persons may be assigned to such workplaces in

the context of an extraordinary vaccination, (b) the cases where before any routine and extraordinary vaccination an individual is obliged to undergo the examination of immunity and a specified kind of vaccination, and (c) the extent of the record of vaccination in a vaccination card or health and vaccination card of a minor and young person and in the medical documentation of the vaccinated person.”

51. Section 2 of the Decree, introduced by the marginal heading Vaccination classification, classifies in paragraph 1 (a) to (e) vaccinations against infectious diseases under (a) routine, (b) extraordinary, (c) emergency, which means the vaccination of individuals to prevent infections in emergency situations, (d) vaccination in the case of injuries, wounds, non-healing wounds, and before some medical procedures, namely against tetanus and rabies, and (e) vaccination carried out at the request of the natural person who wishes to be protected by vaccination against infections for which there is a vaccine available. As for routine and extraordinary vaccinations, diseases against which the two types of vaccinations are performed are enumerated. Pursuant to paragraph 2 of the same provision, the routine vaccinations are carried out as either (a) primary or (b) booster; with both vaccinations, one or more doses of vaccines are administered to achieve the desired effect.

52. The provisions of Sections 3 to 7 of the Implementing Decree set out the regulation of the procedure of routine vaccinations against diseases identified therein, including the period when the vaccination is to occur. The regulation of extraordinary vaccination follows (Sections 9 to 11, Section 13), requiring the characteristics of workplaces, as well as persons (job functions), for which the vaccination is to be carried out, follows. The provisions of Sections 14 to 18 regulate the common conditions of the performance of vaccination (tools, vaccines), the conditions of passive immunisation (administration of other agents in addition to vaccines), the definition of workplaces with a higher risk of infectious diseases, the conditions for the assignment of natural persons to the workplaces, and the extent of the record of vaccination in vaccination or health cards of minors and young persons. This is followed by transitional and annulling provisions of the Decree.

IX.

The case-law of the vaccination obligation in relation to fundamental rights and freedoms

53. In the resolution of its extended panel of 3 April 2012, ref. No. 8 As 6/2011-120 (No. 2624/2012 of the Collection of the Supreme Administrative Court), the Supreme Administrative Court dealt with a contradiction in the legal opinions of the court’s panel in the assessment of situations where a child was not accepted into a preschool as a result of the absence of vaccination against three childhood diseases and penalties have been imposed upon the parents for their refusal to give their consent to the routine vaccination of their children. In this context, the necessity has arisen to answer the question whether the legal regulation of compulsory vaccination against infectious diseases stands in terms of content or a proportion of requirements included in the provisions of Section 46 of Public Health Protection Act on one hand and their specification in the Implementing Decree on the other hand. The Supreme Administrative Court concluded that “the framework regulation of the obligation of natural persons to undergo vaccination provided for in Section 46 of Act No. 258/2000 Coll., on the protection of public health, and its specifications in Decree No. 537/2006 Coll., on the vaccination against infectious diseases, corresponds to the constitutional requirements under which obligations may only be imposed by law and within its limits (Article 4 (1) of the Charter of Fundamental Rights and Freedoms) and the limits of fundamental rights and freedoms may be regulated only by law (Article 4 (2) of the Charter of Fundamental Rights and Freedoms).”

54. The Supreme Administrative Court stated in the cited resolution that Article 26 (1) of the Convention on Biomedicine, inspired by similar texts of the European Convention, is part of the international human rights treaty and implies the principle of the limitation of the fundamental rights only by law. However, the court noted the interpretation of this requirement: it does not always have to be under any law, but also “legal order” in the substantive sense (including e.g. the established case-law), which has a certain quality and, as a legal rule, is typical for its accessibility, sufficient clarity, and predictability. The requirements of Article 4 (1) and (2) of the Charter concerning *reservatio legis* in imposing obligations have been fulfilled in the case under consideration in the view of the Supreme Administrative Court. The court considered Section 46 of the Public Health Protection Act in terms of defining the extent of the vaccination obligation as constitutional and the regulation of details in the Implementing Decree as in accordance with the requirement that the vaccination obligation and its limits should be regulated by law and the practical application of the obligation should be implemented by the implementing regulation. Although the extended panel granted certain legitimacy to the objection of one of the competing panels that the Implementing Decree contains more details in comparison with other implementing regulations, it did not consider this as a qualitative difference which would result in the unconstitutionality of the legal regulation under consideration. The legislature pursued legitimate reasons when defining in Section 46 of the Public Health Protection Act the vaccination obligation generally and leaving the determination of cases and

dates when such obligation should be fulfilled up to the implementing legislation. The extended panel of the Supreme Administrative Court stated that “the matter of whether and to what extent the vaccination obligation should be determined has not only professional aspects but also political ones since this obligation always constitutes certain limitation of the mentioned fundamental rights and freedoms, while views on the benefits or, conversely, some undesirable effects of vaccination in specific cases may differ in the society”.

55. The complainants have not made the objection to a violation of the fundamental right to life under Article 6 of the Charter (Article 2 of the Convention) the subject of their constitutional complaint. This right is associated, among others, with a positive commitment by the state to take the necessary measures to protect the lives of patients in the implementation of health care. Besides the measures leading to an immediate saving of life, preventive measures should also be adopted. However, the case-law of the ECHR (cf. also the case of *Solomachin v. Ukraine*) does not affirm the eventuality according to which the implementation of the institution of compulsory vaccination against infectious diseases is causally connected with Article 2 of the Convention (for more details, see Drgonec, J. Povinné očkovanie verus základné práva zaručené Ústavou Slovenskej republiky (Compulsory Vaccination versus the Fundamental Rights Guaranteed by the Constitution of the Slovak Republic). *Justičná revue* No. 2/2014, pp. 226 to 227, and a decision of the Commission of the ECHR in the case of *X v. Austria*, of 13 December 1979, No. 8278/78, cited therein).

56. When assessing the relationship between the legal regulation of compulsory vaccination and the fundamental rights and freedoms, it is necessary to accentuate Article 7 (1) of the Charter according to which the inviolability of person and privacy are guaranteed and may only be limited in the cases specified by law. The injection of the vaccine into the human body which is to bring forth an immunity system response with a long-term effect is an interference with bodily integrity. Article 7 (1) of the Charter specifies more general guarantees of the protection of privacy and family life against any unlawful interference as guaranteed by Article 10 (2) of the Charter. The right to the inviolability of person and privacy is important due to its position in the structure of the Charter; it is a provision in the foreground of modifications of the basic human rights, which has in a hierarchical structure of objective values of the constitutional order, as a guarantee reflecting a “traditional” fundamental right, a higher importance than only the rights only derived from the constitutional soft law [see the judgment of the Constitutional Court, file No. I. ÚS 823/11, of 6 March 2012 (N 44/64 of the Collection of Judgments of the Constitutional Court 521)].

57. Another provision of the fundamental right which is directly related to the regulation of compulsory vaccination against infectious diseases is Article 16 of the Charter (cf. Item 43) concerning the freedom to manifest religion or belief and the autonomy of churches, already part of the case-law of the Constitutional Court. The judgment, file No. III. ÚS 449/06, resulted in a legal sentence, according to which “the principle based on the requirement to preserve the maximum of a fundamental right as well as the public interest colliding with the fundamental right is reflected in the interpretation of Article 16 (4) of the Charter of Fundamental Rights and Freedoms according to which the fundamental protection of individual autonomy required by the Constitution of the Czech Republic, as assumed by the cited provisions, requires that the compulsory vaccination not be enforced against the obliged persons in exceptional cases”. It is fitting to note that the Constitutional Court based its approval of this exemption from the compulsory vaccination to the considerable extent on the statements of the Committee on Human Rights and Biomedicine of the Council of the Government of the Czech Republic for Human Rights that has acted as *amicus curiae* in the proceedings concerning the constitutional complaint. The Committee on Human Rights and Biomedicine said that given the high level of vaccination coverage of the population (higher than expected 90%) an extraordinary failure to force any vaccination, bearing in mind the exceptional circumstances of the case, cannot jeopardize the constitutionally protected interest in the protection of public health. The Constitutional Court, later in the reasoning of the judgment which, among other things, annulled the judgment of the Supreme Administrative Court, stating that Article 16 of the Charter has been interfered with, inferred the complainant’s fundamental right to express freely his/her religion or belief within the meaning of Article 16 (1) of the Charter. It admitted, however, that the exercise of this fundamental right is not non-limitable but is subject to legal limitations under Article 16 (4) of the Charter (measures necessary in a democratic society for the protection of public safety and order, health, morals, and the rights and freedoms of others). The Constitutional Court has decided in favour of the complainant with regard to Article 32 (4) concluding that the complainant’s fundamental right under Article 16 (1) of the Charter is in this case also complemented by a fundamental right of the complainant as a parent.

58. In the general context of the interpretation of fundamental rights in relation to the compulsory vaccination, it is desirable to note that the complainants’ objection to interference with the right to protection of health (the first sentence of Article 31 of the Charter) is undoubtedly important but not decisive. A particular interest of parents in protecting the health of their child certainly cannot be overlooked. However, there is a wider interest in the

protection of public health against the parents' interest, manifested in the preventive nature of the vaccination of the whole population performed with the legitimate aim of preventing the incidence and spread of infectious diseases among people. The emphasis of legal order on the protection of health consists here in a positive obligation of the state to contribute with specific measures to the protection of the health of its citizens (cf. Wagnerová, E.; Šimíček, V.; Langášek, T.; Pospíšil, I. et al. *Listina základních práv a svobod. Komentář*. (The Charter of Fundamental Rights and Freedoms. Commentary.) Prague: Wolters Kluwer ČR, 2012, page 645, Article 31 of the Charter commented by J. Wintr).

59. Pursuant to the first sentence of Article 32 (4) of the Charter, caring for and upbringing their children is the right of parents; at the same time, the children have the right to that parental upbringing and care. The Constitutional Court has expressed a legal opinion in its case-law that the autonomy of parents when deciding on medical procedure performed on their children is not absolute. It may exceptionally be limited, even if the parents do not agree with a medical procedure on the grounds of religion [see the judgment of 20 August 2004, file No. III. ÚS 459/03 (N 117/34 of the Collection of Judgments of the Constitutional Court 223)]. Protecting the health and life of children is relevant and a more than sufficient reason for an interference with parental rights because it is a value the protection of which enjoys priority in the system of fundamental rights and freedoms. The ordinary courts are then obliged to seek in their decisions concerning specific cases consistency between the interests of children and those of their parents.

X.

Reservatio legis

X./a Case-law postulates

60. The Convention uses in connection with the requirement for the necessary legal regulation of the matter the phrases like "prescribed by law" (e.g. in Article 9 (2)), "provided for by law" (in the second sentence of Article 1 of Report No. 1) or "in accordance with law" (Article 2 (3) of Report No. 4); the French version also uses various phrases, such as "prévüe par la loi" (Article 8 (2) of the Convention). The European document refers in all cases not only to "law" but also "legal order". The formulation implementing *reservatio legis* must be set by the legal order in the substantive sense of the word and not only written law but also unwritten law and judicial law may be subsumed under it (see *Sanoma Uitgevers B.V. v the Netherlands*, judgment of the Grand Chamber of the ECHR of 14 September 2010, No. 38224/03). In view of the ECHR, the written law includes not only laws but also legal regulations of lower legal force, the prescriptive acts issued by professional organisations, and other similar sources (see *Sanoma Uitgevers B.V.*, as well as *Leyla Şahin in Turkey*, judgment of the Grand Chamber of 10 November 2005, No. 44774/98).

61. *Reservatio legis* requires that the fundamental issues of the matter be regulated by laws and that the legal regulations applicable to the issues contain at least the elements and their consequences; the more important the regulated matter is the more detailed the legal regulation must be. The legal regulation fulfilling the requirement of *reservatio legis* assumes such clarity that its recipients are able to understand its content and effects and adapt their behaviour including anticipating its consequences (see the commentary cited in paragraph 58, pages 25, 129, by E. Wagnerová).

62. The formal and substantive requirements for the secondary law-making and thus also its differentiation in relation to the content of the "original" law are summarised by the judgment of the Constitutional Court of 14 February 2001, file No. Pl. ÚS 45/2000 (N 30/21 of the Collection of Judgments of the Constitutional Court 261, 270; 96/2001 Coll.). According to the judgment, the constitutional definition of the derived law-making by the executive power is based on three principles. These are the issue of a secondary regulation (an implementing regulation, namely a Government order in the cited case) by the competent authority, a ban for the regulation to interfere with the matters reserved to law (it cannot determine any primary rights and obligations), and the existence of express intention of the legislature to regulate beyond the statutory standard (there must be open space for the sphere of derived regulations).

63. The relation between any law and an implementing regulation was described by the Constitutional Court in the judgment of 16 October 2001, file No. Pl. ÚS 5/2001 (N 149/24 of the Collection of Judgments of the Constitutional Court 79, 89; 410/2001 Coll.). It concluded that "the contested regulation does not violate *reservatio legis* as it specifies only based on the express statutory authorisation the matter regulated by law itself as for the main features. The opposite conclusion that would require the determination of any obligation directly and exclusively by law would obviously lead to absurd consequences, namely the denial of the meaning of the secondary (and in some cases also the primary) law-making since the conceptual part of every legal regulation is defining certain rights and obligations of the recipient of the regulation."

X./b Assessment of the legal text

64. The extended panel of the Supreme Administrative Court considers in the resolution, file No. 8 As 6/2011 (paragraphs 53 and 54), as decisive that Section 46 (1) of the Public Health Protection Act imposes upon the unambiguously certain groups of natural persons the obligation to undergo any routine vaccination or extraordinary vaccination. This is connected with the obligation as set out in paragraph 2 according to which it is necessary to undergo before any vaccination the examination of immunity (resistance) or to respect the health condition findings that prevents the administration of vaccine (permanent contraindication). The following paragraphs 3 to 5 deal with the related issues (a decision on the obligation to undergo examination, a legal representative responsible for the person who has not reached the age of fifteen years, and cooperation of a public health authority with a health care provider). The last paragraph 6, in accordance with the previous ones, delegates to the Implementing Decree (see also Section 108 of the Public Health Protection Act) the classification of vaccination under individual types and conditions of vaccination. The Supreme Administrative Court concludes that Section 46 of the Public Health Protection Act sets for the selected groups of natural persons, in a general but sufficiently clear and certain manner, the vaccination obligation (irrespective of the kind of vaccination) and the related obligation to undergo before the vaccination the examination of the immunity of the body, or follow such conclusion of the examination which prevents the administration of the vaccine. The Implementing Decree then specifies, *inter alia*, against which infectious diseases and on which dates the obligation to undergo a certain type of vaccination becomes effective (especially routine vaccination, extraordinary vaccination or emergency vaccination) and also regulates other details.

65. The Constitutional Court emphasises that Section 46 (1) of the Public Health Protection Act gives the definition of a natural person who is obliged to submit to the appropriate vaccination obligation. The definition contains the necessary parameters relating to such person, namely the permanent residence of a Czech national and the right of permanent or temporary residence of a foreign national, with a minimum length of residence of 90 days. The types and terms of routine vaccinations are defined in the Implementing Decree; by analogy, the determination of the circle of natural persons and workplaces subject to the obligation to undergo an extraordinary vaccination is delegated to the implementing regulation. Such regulation is correct and sufficiently distinguishes what aspects already exceed the necessary degree of generality.

66. Part of the legal definition of the person obliged to undergo vaccination is a responsibility of the legal representative of the person under the fifteen years of age, as laid down in paragraph 4. Similarly, paragraphs 2 and 3 of Section 46 of the cited Act are formulated so that the recipient of the legal regulation should be able, without any doubt, to see that he/she is obliged to undergo the examination of his/her immunity, which can lead, as well as other findings concerning his/her health state, to the conclusions preventing the administration of vaccine (permanent contraindication). In the event that a minor does not undergo vaccination or previous examination and has not chosen a general practitioner, the obligation to undergo vaccination or examination with a designated physician (a health care provider) is imposed through a decision of public health protection authority. Also this wording of the legal regulation is specific enough and comprehensible according to the Constitutional Court. The remaining paragraphs of Section 46 impose upon health care providers the obligation to perform the examination and vaccinations (paragraph 5) and empower the Implementing Decree to modify the classification of vaccination, conditions of vaccination, methods of immunity investigation, and details of extraordinary vaccinations (paragraph 6), which are obviously part of the legal regulation, all of which regulate the implementation phase of vaccination obligation and should be included in the text of the Implementing Decree.

67. The complainants' objections are directed against the insufficient legal regulation (Section 46) of the extent of vaccination and its method. The complainants consider that the text of law does not imply the extent of the vaccination clearly as needed. In their opinion, its regulation is contained in the Implementing Decree, namely Section 2 concerning the classification of vaccination. Only the mentioned provision enumerates individual types of vaccination and is followed by a list of diseases against which the vaccination is performed (then the routine vaccination is classified under primary vaccinations and booster vaccinations). A similar complaint is expressed as to the manner of vaccination. It is pertinent to note that the specific procedures of performance of individual types of vaccination against the enumerated diseases are governed by the provisions of Sections 3 to 17 of the Implementing Decree.

68. However, it cannot be concluded, with necessary emphasis on the universality of the legal regulations, that the extent of vaccination has not been regulated by law with the necessary level of detail. Each of individual types of vaccinations enumerated in Section 2 of the Implementing Decree, whether it is a routine vaccination, an extraordinary vaccination or an emergency vaccination, a vaccination during accidents and injuries, a

vaccination before certain medical procedures or a vaccination required by a natural person, is inevitably associated with very specific diseases, circumstances conditioning specific kinds of vaccination, subsequent time vaccination requirements, as well as defining specific reasons for vaccination (vaccination before medical procedures) or imposing certain job positions (extraordinary vaccination). The latter particular facts thus become justified part of the implementing regulation. The classification of the legal regulation requires here that the regulation of various types of vaccination should not be separated from the very specific and often historically conditioned facts related thereto (including the state of the art). Therefore, there can be found no defect of the legal regulation as to the extent of vaccination, which could result in its constitutional non-conformity.

69. A similar conclusion is reached by the Constitutional Court in relation to the complainant's objections as regards the determination of the manner of vaccination; it should not have been described in the Implementing Decree but in law. The modification of the manner of vaccination is already *prima vista* attributable not to the general legislation but to the implementing regulation. Moreover, the implementing regulation - and this is important to emphasise - predominantly sets out the conditions of the performance of various kinds of vaccination against specific diseases.

70. With the help of linguistic and systematic interpretation, it might be justifiably concluded that the text of Section 46 of the Public Health Protection Act is sufficiently clear and comprehensible and reliably imply basic attributes and limits of the legal regulation of the compulsory vaccination against infectious diseases. The authorisation which is provided to the Implementing Decree to regulate the details associated with the performance of compulsory vaccination is applied by the secondary regulation within the given limits without interfering with the elements contained in the substantial features of law. Therefore, there has been no legislative interference with the guarantees provided to the holders of fundamental rights and freedoms under Article 4 (1) and (2) of the Charter.

X./c Investigation of the nature and meaning of fundamental rights

71. When assessing the constitutionality of the legal regulation, it is not possible to ignore the categorical postulate of Article 4 (4) of the Charter according to which the application of the provisions concerning the limits of fundamental rights and freedoms deals with their nature and meaning and their limits may not be used for purposes other than those for which they have been provided. The compulsory vaccination against infectious diseases constitutes an interference with the bodily integrity of an individual, as well as an interference with his/her privacy and family life, where appropriate. As a limitation of a fundamental right, the institution of vaccination obligation must be accompanied by such legal guarantees which would minimise its abuse and eliminate the medical procedure in the event that there are no conditions for its implementation. Without intending to interfere with the technical aspects of the performance of vaccination, the Constitutional Court notes that it regards paragraphs 2 and 3 of Section 46 of the Public Health Protection Act as such guarantee. As mentioned above, a natural person is obliged to undergo in the cases provided for in the implementing regulation the examination of immunity (resistance) before the performance of any routine or extraordinary vaccination. The routine and extraordinary vaccination shall not be carried out if any finding of the examination of immunity or health condition prevents the administration of vaccine (permanent contraindication) in both cases. These facts shall be the subject of confirmation issued by the health care provider to a natural person and the reason for abandoning the vaccination should be recorded in his/her medical records. If the competent authority in charge of the protection of public health establishes that a minor natural person has failed to undergo vaccination or examination pursuant to paragraph 2 and it is a minor natural person who has not chosen a general practitioner, the authority shall impose upon that person through its decision the obligation to undergo vaccination or examination with the designated physician. The legal regulations is followed by the Implementing Decree containing at more places the specific obligations of health care provider defined in detail, the fulfilment of which is to ensure that the vaccination shall be done properly. These are intervals between individual vaccinations and monitoring the response to the first of vaccinations carried out, etc. (Section 3 (2), Section 5 (2), and Section 14 (2) of the Implementing Decree). The thus summarised content of the legal regulation pursues the objective of ensuring that the compulsory vaccination against infectious diseases is carried out properly and does not reduce the limit of limitations for a natural person at the expense of preserving the nature and meaning of the fundamental right within the meaning of Article 4 (4) of the Charter.

XI.

Test of the limitation of fundamental rights

72. The complainants have found in the petition seeking the annulment of legal regulations the causal link between an administrative penalty imposed upon them and a legal obligation to undergo vaccination against infectious diseases. In this respect, the Constitutional Court notes that the legal regulation of compulsory

vaccination uses the space given to the national legislations under Article 26 of the Convention on Biomedicine, also respected by the European case-law, and that its judgment, file No. III. ÚS 449/06, has clearly and positively commented on the validity of this regulatory mechanism.

73. Should the further described test of the limitation of the fundamental right be carried out despite that, it is done for the reason that the most important fundamental right, which is limited by the legal regulation of compulsory vaccination, is the right to privacy in the form of the guaranteed inviolability of person (Article 7 (1) and Art 10 (2) of the Charter); such person is obliged to suffer an interference with his/her bodily integrity in the form of a medical procedure under the legal conditions. In order to review the human rights conformity of the legal regulation of the limitation of the right to privacy, including an interference with bodily integrity, accompanied by the limitation clauses concerning the conditions of permissibility of the limitation of privacy by the state, the case-law of ECHR uses a five-stage test (for details, see Kmec, J.; Kosař, D.; Kratochvíl, J.; Bobek, M. *Evropská úmluva o lidských právech. Komentář.* (The European Convention on Human Rights. Commentary.) Issue 1. Prague: C. H. Beck, 2012, pp. 99 to 116, commented by D. Kosař).

74. The first step of the test is to examine whether the discussed case falls within the substantive scope of those rights which are limited. The answer to this question is obvious. The sphere of protection of the fundamental right to privacy and family life includes the guarantees provided to individuals that the state has an obligation to respect and only interfere with them in unavoidable cases. If the medical procedure interferes with the right to the inviolability of person, without it being any interference due to his/her disease, while as for persons younger than 15 years of age the legal representatives of the child bear responsibility for that interference, then it is only natural to deal with the limitations that should be subject to the respective test.

75. The second question of the test seeks to determine whether any fundamental human right has actually been interfered with in a particular case. Also this answer must be positive. The requirement shall be deemed fulfilled upon any interference with the bodily integrity of the vaccinated person with any expected long-term effectiveness. In the case of compulsory vaccination of a minor under the age of 15 years, also the right of legal representatives (parents) to decide on the care for and upbringing of their children (Article 32 (4) of the Charter) shall also be limited. Moreover, the Constitutional Court also ruled in its judgment, file No. III. ÚS 449/06, on the possibility of interference with the fundamental right to freedom to manifest religion or belief.

76. The third step of the test is to review the legality of limitation of the right to privacy. The desirable lawfulness (legality) of the limitation of the fundamental rights is based as for the content on the principle of the limitation of fundamental rights as prescribed by law and expressed in Article 4 of the Charter. The issue related to the limitation of fundamental rights by law in the cases of compulsory vaccination against infectious diseases is regulated by Items 60 to 71 of this judgment, with a positive conclusion on the legality of statutory limitations.

77. The fourth step of the test raises the requirement for the legitimacy of the limitation of the fundamental rights at issue. The European question reads as follows: Does the interference with the human right pursue at least one of the permitted legitimate objectives? The typology and a list of legitimate objectives have been established by the case-law of the ECHR as a result of the generalisation of jurisprudence practice (cf. the commentary cited in paragraph 73, pp. 110 to 111). One of the recognised legitimate objectives is the protection of health, while the purpose of compulsory vaccination is not only the blanket vaccination of persons *ex lege*, but also indirectly the protection of natural persons against infectious disease, who have not been vaccinated for various reasons.

78. Without any doubt, the most important, namely the fifth, step of the test is to answer the question of the necessity of limiting a fundamental right by law (without any uniform and binding algorithm for the assessment of this issue being adopted by the case-law of the ECHR). Precisely the question of the necessity of compulsory vaccination in a democratic society is put by the complainants in their petition.

79. The Constitutional Court does not consider as part of the review authorisations the assessment of technical aspects of the issue, including those reasons which have resulted, in the light of medical science, in the introduction of partial or blanket vaccination of the population, including the application of the institution of compulsory vaccination provided for by law. It is not the role of the Constitutional Court to decide whether the epidemiological situation in any country of Europe allows the modification of the compulsory vaccination or not. Although the use of expert knowledge is an alternative here, the assessment of those sources belongs to the legislative and executive sphere of action. The Constitutional Court therefore proceeded from the generally accessible sources of competent institutions, both international and Czech ones. Their apparent conclusions speak in favour of the adopted solution of blanket vaccination against some infectious diseases and the interest in protecting the public health outweighs the complainants' argument against the compulsory vaccination.

80. The statement of the Ministry of Health concerning the complainants' constitutional complaint under file No. I. ÚS 1253/14 (dealt with separately as a particular case beyond the constitutional control of law) statistically documents a substantial reduction in or disappearance of morbidity after the (available) compulsory preventive vaccination has been administered. Measles, poliomyelitis (polio), and diphtheria are given as examples. As for measles in 1953, the morbidity amounted to 350 persons per 100,000 inhabitants and gradually increased up to 900 people; upon the commencement of vaccination in 1969, it amounted to approximately 600 people, and after the introduction of two doses of vaccine, except for small deviations in the early nineties of the last century, the morbidity decreased to zero. As for polio, the number of reported diseases has exceeded 2,000 people at the end of the forties of the last century. After the commencement of vaccination against the disease in 1957, the disease disappeared in 1961. The maximum people with diphtheria was recorded in 1946, namely over 500 per 100,000 people. Since the commencement of vaccination against the disease in the sixties of the last century, there has been no considerable incidence of this disease.

81. The recommendations of the World Health Organization (WHO) for Europe including the statistical data until 2011 contain seven points of vaccination strategy emphasising the preventive effect of vaccination. As demonstrated especially in items one and four, high vaccination coverage leads to reducing the incidence of the given disease and it is a guarantee of minimising the incidence or spread of epidemics. According to the comparative tables published as to the cited paragraphs, the vaccination coverage achieves the desired level of approximately 95% (source: http://uvzsr.sk/docs/info/epida/Seven_Key_Reasons).

82. In 1997, the recommendation titled Vaccination in Europe as a document of the Parliamentary Assembly of the Council of Europe was published under No. 1317. The text of the recommendation calls upon the Committee of Ministers to invite the Member States to introduce a comprehensive public vaccination programmes as the most effective means of preventing infectious diseases. The recommendation notes in its introduction that in certain countries of Central and Eastern Europe the fall of totalitarian regimes has caused the disintegration or even the dissolution of health care state systems and, as a result, among other things, an increased incidence of infectious diseases (the text is available at <http://assembly.coe.int>, for details see Doc. 7726, Report of the Committee on Social, Health and Family Affairs, adopted on 19 March 1997).

83. The Council of the European Union adopted at its meeting concerning health issues on 6 June 2011 in Luxembourg conclusions titled Childhood Immunisation: Successes and Challenges of Childhood Immunisation in Europe and Way Forward. The document is based on Article 168 of the Treaty on the Functioning of the European Union, according to which national policies on the issues of public health should be consistent. This refers to Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004 establishing the European Centre for Disease Prevention and Control (http://consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/lsa).

84. The Constitutional Court concludes as to the five-stage test of the limitation of fundamental rights applied to the necessity for the limitation of the right to the inviolability of person through the legal regulation of the institution of compulsory vaccination that compared to the arguments of the complainants the Czech and international sources and recommendations concerning the matter place emphasis on the requirement for public vaccination programmes including the childhood immunisation, namely in order to minimise the spread of infectious diseases in the interest of public health protection. The institution of compulsory vaccination which is fully in the responsibility of the national legislature serves the implementation of this requirement. The test thus stands in favour of the existing legal regulation.

XII.

Conclusions

85. Comparing the interest in the protection of public health and the fundamental rights and freedoms that are or may be affected by the compulsory vaccination against infectious diseases is a polyvalent matter also because the fundamental rights also include human, civil, and social rights. The Constitutional Court hereby makes in relation to Section 46 of the Public Health Protection Act the annulment of which the complainants have sought general conclusions concerning its compliance with the principles of the Constitution and the Charter, without interfering with expert or political spheres. The public interest in relation to the fundamental rights may be assessed at the level of constitutional review of the legal regulation of compulsory vaccination in terms of necessity. The review applies to the general statutory guarantees of the procedures of compulsory vaccination, while the determination of detailed rules of compulsory vaccination, based on expert knowledge, must be, even

bearing in mind their impact on the circumstances of an individual, left to the executive field and the conceptual considerations of legislative policy.

86. The current legal regulation of the issue of compulsory vaccination against infectious diseases allows responding to the development of the incidence of individual infectious diseases in any country sufficiently quickly, as well as responding to the state-of-the-art knowledge in the fields of medicine and pharmacology. This is reflected in amendments to Decree No. 537/2006 Coll., on the vaccination against infectious diseases (No. 65/2009 Coll., No. 443/2009 Coll., and No. 299/2010 Coll.), and the previously valid Decree No. 439/2000 Coll., concerning the same issue, which have amended the extent of compulsory vaccination.

87. The Constitutional Court considers it desirable to express an opinion on the subject of its review also *obiter dictum*. Its positive conclusions on the fulfilment of *reservatio legis* and the necessity of the legal regulation of compulsory vaccination have exhausted the scope of the review and have not entitled the court to assess the complainants' objections (in fact, formulated *de lege ferenda*) to the absence of the legal regulation of the state's liability for damage caused to individuals by vaccination. If, however, the state provides for a penalty in the event of the refusal to submit to the obligation to undergo vaccination, it must also consider the situation where the vaccinated person suffers an injury to health as a result of the enforcement of law by the state. The space required to compensate such person is reopened by the Convention on Biomedicine which is part of the constitutional order and, in Article 24, mentions "fair compensation" for "inadequate injury" to health caused by any medical procedure as provided by law. Part of the consideration concerning the compensation may also be the legal regulation of material and non-material damage under the Civil Code. However, the fact that the compulsory vaccination is a medical procedure of a preventive nature, done in the interests of public health, approved by law, and having an extraordinarily wide personal range and impact, cannot be ignored. These circumstances make it difficult for the legal position of a person who may sustain an injury to health as a result of vaccination and it is therefore necessary that the legislature should consider an amendment to the legal regulation of the institution of compulsory vaccination against infectious diseases by the regulation of the state's liability for the consequences mentioned above. It should occur even more so when such legal regulation is not exceptional whatsoever in other states (cf. the appropriate objection addressed in this respect to the legislature by the Constitutional Court of Slovenia in the decision of 12 February 2004, file No. U-I-127/01).

88. Part of the complainants' petition seeking the annulment of legal regulations was also the petition seeking the annulment of Section 29 (1) (f) of the Act on Administrative Offences, specifically the petition seeking the deletion of the text concerning a violation of the ban or obligation set out or imposed to prevent the incidence and spread of infectious diseases. Neither this petition could be complied with. The reason for this is the subject-matter elements of the administrative offence the annulment of which the complainants have sought. As is evident from the wording of the Public Health Protection Act, any failure to comply with any obligation or ban connected with the compulsory vaccination is only part of the elements. Penalties may be imposed here also for administrative offences involving other acts than failure to submit to the vaccination obligation (see the violation of obligations under Sections 45 to 75b of the Public Health Protection Act, e.g. the obligation to take and comply with anti-epidemic measures, to isolate patients in isolation wards, etc.).

89. For all the foregoing reasons, the Constitutional Court has found no grounds for the annulment of the respective legal regulations since the fundamental rights guaranteed by Article 2 (3) of the Constitution, Article 9 of the Convention, and Article 2 (2) and (3), Article 3 (3), Article 4, Article 7, Article 10, Article 11, Article 15, Article 31, and Article 32 (4) of the Charter have not been infringed upon by them. Therefore, the Constitutional Court has dismissed to the full extent in accordance with Section 70 (2) of the Act on the Constitutional Court the petition seeking the annulment of Section 46 of the Public Health Protection Act and the annulment of Section 29 (1) (f) of the Act on Administrative Offences.

Appeal: No appeal is permissible against the judgment of the Constitutional Court.

In Brno on 27 January 2015

A dissenting opinion of Judge Kateřina Šimáčková on the verdict and reasoning of the judgment, file No. Pl. ÚS 19/14

1. Vaccination obligation as such

1. In most Western European countries where the protection of human rights and the respect for freedom and individual autonomy are at the highest level (e.g. Austria, Germany, Spain, the Netherlands, Denmark, Finland, Iceland, Ireland, Luxembourg, Norway, Portugal, Sweden, the United Kingdom, Canada), there is no statutory vaccination obligation. The adequate vaccination coverage of the population is ensured on one hand by good physicians who are able to convince a sufficient number of the parents to have their children vaccinated and, on the other hand, the responsible parent who can benefit from the freedom while manifesting the responsibility for the health of their children and others.

2. I am of course aware that in the currently very paternalistic medical care in the Czech Republic not all physicians are able or willing to ensure that the parents are informed in a quality manner and to persuade them to have their children vaccinated voluntarily, and that the protection of public health as an important public interest would not be ensured if the obligation to undergo vaccination against all infectious diseases would be immediately cancelled without any replacement. However, the long-term objective of state that respects the freedom of its citizens should be that all medical procedures are performed on the basis of free and informed consent and, as regards the procedures performed on children, the consent should be obtained principally from their parents if the children are so young that it is not possible to secure such consent from them.

3. However, if the vaccination obligation should be preserved in order to achieve the target state, the existing legal regulation is not constitutionally conforming for a number of reasons mentioned below (sections 3 and 4 of this opinion).

2. The ideology behind the issue of compulsory vaccination and certain other medical and legal issues in the Czech Republic

4. According to the self-assessment of our health professionals and from the point of view of the major part of the society, the medical care is at an exceptionally high level in the Czech Republic. The people like to rely on the care of physicians (especially if they prescribe drugs and medical procedures and do not require from them any regime measures or lifestyle changes). Especially the recognised successes of the Czech medicine and pride in the achievements of medical care dating back to the time of real socialism then lead to the paternalistic approach of physicians to patients, which is currently required by most patients. The patients who do not welcome such approach and who require a more partnership approach form a tiny minority and are considered mavericks who do not know when one is well off. Their objections or requests may be downplayed by physicians and ridiculed by others. The lack of understanding on both sides then leads to the escalation of conflicts demonstrated at most in the issues of human reproduction and medical care for pregnant and labouring women and children. Adult patients who feel unwell in a tight embrace by the lovingly caring paternalistic state could usually cope with it somehow. But in the event of care for the unborn or new-born children, or even older children, the state and the majority of society and health care professionals consider it their obligation to enforce what they consider as the best care, without any compromise or explanations, and sometimes even by force. The parents under pressure then start to worry about their children. It is in those emergency situations or conflicts when misunderstanding on both sides stubbornly persist. The lack of friendly and explanatory approach from a part of medical staff then result in a number of suspicions, fears, and misunderstandings on the part of the alternative minority, and even sometimes in strong statements, which in turn even further angers the majority of people and the power elite of the society.

5. Should a judicial authority enter this complicated and precarious social situation, it should do so free of any ideological bias and under the same rules as in all other cases. I am afraid, however, that this has not occurred in the present case. Although the existing legal regulation of the vaccination obligations has a number of constitutional deficits which are described below and which are admitted by some authorities, the majority of the judges of the Constitutional Court feared that their statement annulling the legal regulation or any part thereof could be construed as an endorsement of the above-mentioned alternative minority who criticises the health care in our country. In this case, however, the role of the Constitutional Court has not been to assess the quality of health care in the Czech Republic or judge parents causing harm to their children, but to assess, without prejudice and with cool heads in terms of their expertise, the constitutionality of the contested legal regulation. It is not a role of the court to stand on either side of any social conflict but to protect the constitutionality in a quality manner and convincingly as in all other cases.

3. Violation of *reservatio legis* expressly set out by the Constitution

6. I see the simplest and basic unconstitutionality in the violation of *reservatio legis* as set out in Article 7 (1) of the Charter, which states unambiguously that any interference with bodily integrity must be performed only by law, not by a ministerial decree.

7. Any comparison with the practice of other states or the case-law of the ECHR and other constitutional courts will not stand in the light of the clear wording of Article 7 (1) of the Czech Charter of Fundamental Rights and Freedoms, which provides that the inviolability of person may only be limited in the cases specified by law. The protection of bodily integrity and vaccination as interference with the bodily integrity falls under this provision of the Charter, as stated after all as well as by the majority in Item 56. In this context, I note that the issue whether we are entitled to the payment for two or three weeks at spa must be subject to law according to the case-law of the Constitutional Court [see the judgment, file No. Pl. ÚS 43/13, of 25 March 2014 (77/2014 Coll.)], but the extent of interference with bodily integrity (injection of foreign substances into the body of children using a needle) is left to a ministerial decree, without the conditions of the vaccination obligation and the diseases subject to the obligation being defined by law. The statutory authorisation contains neither the nominal list of diseases against which the vaccination is compulsory nor the criteria binding on the ministry while determining the extent of the vaccination obligation.

8. *Reservatio legis*, a formal one at first glance, has great substantive contents. The current practice leaves to the expert unjustified decisions hidden in the public all the important issues associated with the vaccination - namely the extent of compulsory vaccination and its timing. This decision-making is not public, which, as in other areas, raises suspicion and, moreover, leads to the fact that the public does not learn the reasons for the given regulation and amendments thereto. In the absence of the form anticipated by the Charter, any convincing explanatory memorandum setting out the reasons for the specified vaccination obligation and its purposes (for the testing of proportionality and legitimate objectives of the legal regulation) is missing. The essence of *reservatio legis* is that any interference with the rights of individuals should not only be done based on an expert decision, but should also be subject to an open democratic deliberation in the parliament.

9. Moreover, one cannot agree with that the compulsory vaccination is purely an expert matter. An expert matter is, as with virtually every legal regulation, the supply of information needed for a decision, for example, how a given disease is dangerous, how infectious and, therefore, contagious it is, how effective the vaccine is, etc. However, whether in a given situation, the protection of public health outweighs the individual's right to bodily integrity, i.e. finding the optimal balance between these competing interests, is a political and legal matter. The existing case-law of the Constitutional Court regarding *reservatio legis* within any interference with fundamental rights, which is, however, completely ignored by the majority, is also based on the distinction. According to the case-law, the expert matters (cf. the examples from the recent times below) may be regulated by the secondary legislation, however, the political issues, including the establishment of the balance between the constitutionally protected interests, must be governed by law.

According to the judgment, file No. Pl. ÚS 36/11, of 20 June 2013 (standard and above standard health care), the “Charter includes the provisions on fundamental rights, which are different in terms of prescriptive content. Firstly, these are fundamental human rights resulting directly from the human being and only this fact is the basis of the definition of their constitutional content and scope. These are values that contain the fundamental rights to preserve the human integrity and dignity, such as the right to life, the inviolability of person, and personal freedom. Such rights are inherent, inalienable, not subject to the statute of limitations, and irrevocable (Article 1 of the Charter). Their limits may be modified under the conditions prescribed by the Charter and only by law (Article 4 (2) of the Charter)” (Item 38). Even in the case of the right to health, which is a social right, the Constitutional Court has not admitted in this judgment that defining the above-standard health care is left to the secondary legislation. In Item 49 of the reasoning, it stated: “From the perspective of the Constitutional Court, it is however relevant whether the regulation by law itself, therefore without an implementing decree, is clear enough to the recipients and whether it would be applicable. The implementing regulation is to determine only its details. The contested regulation of the alternatives of care currently operates, apart from the above-mentioned general framework under the Public Health Insurance Act, through a decree of the Ministry of Health, issuing the list of medical services with point values, which designates medical procedures for which the insured may be offered a choice between the basic and economically more demanding alternatives. The health care providers, insurance companies, and the insured therefore understand only based on that decree what the standard alternative is and what medical procedures, aids, equipment, and supplies must or may be paid beyond the payment from the public insurance. The law itself does not imply this and it cannot be inferred from it even applying the loosest of interpretations. Therefore, the Public Health Insurance Act did only the first step towards defining the standard and above-standard health care (in the words of the Public Health Insurance Act, the basic and economically more demanding alternatives). The second, however, a substantial part, without which the institution is non-viable, namely the specific determination of what free care is within the meaning of Article 31 of the Charter, is regulated in the Implementing Decree. In view of the Constitutional Court, the legislature has failed to meet the requirements set by the constitutional order repeatedly interpreted in its previous decision-making practice.”

According to the judgment, file No. Pl. ÚS 13/12, of 23 July 2013 (more than a small amount), the aspects of the constitutional definition of the derived regulation-making by the executive power also includes the ban on interfering with the matters reserved to law. In the past and in relation to a legal regulation in a different sphere, the Constitutional Court explained that it is not acceptable to subject the sphere of protection of fundamental rights and freedoms to the jurisdiction of the executive power that is not competent in this respect. The confusion of concepts of law and legal order is therefore excluded in the Czech Republic in the field of fundamental rights and freedoms. The Constitutional Court in this judgment requires that a minimum of “empowering” legal provisions should establish the criteria so that the executive power could only specify and not complement any legal obligation.

According to the judgment, file No. Pl. ÚS 43/13 of 25 March 2014 (Spa Decree), the Constitutional Court demanded that the conditions of the extent (length) of free spa treatment on the basis of health insurance should not only be regulated by the decree as: “time limitations cannot be clearly regarded as a mere specification of conditions ... which must be met should the health care be provided free of charge under the public health insurance and which have the nature of purely technical criteria to be examined by an attending physician or an inspector. Their purpose is to achieve such regulation of the provision of this care, which allows to find a balance between the requirements both for the effectiveness of treatment, i.e. that a spa stay actually fulfils its anticipated medical function, and for its effectiveness and economic viability. The interest in finding this balance is fully legitimate. To achieve this, however, requires not only medical but also economic considerations, which must be recognised the nature of the political decision-making part of which is the assessment of the effectiveness of each of conceivable alternative solutions in order to choose one of them. ... Their determination may, therefore, occur in accordance with *reservatio legis* only through a decision of the parliament” (Item 32).

10. I believe that the matter under consideration cannot be distinguished from the previous case-law the Plenum of the Constitutional Court. Section 46 (1) of the Public Health Protection Act provides only that a certain group of people is obliged to undergo the specified kind of routine vaccinations in the cases and within the time limits under the implementing regulation. This legal framework is quite vague and totally inapplicable without the Implementing Decree. The concerned persons may learn only from the Implementing Decree against what diseases they must be vaccinated and how their right to the inviolability of person is then limited. The law itself even sets absolutely no limits of decision-making of the Ministry of Health as to which diseases the compulsory vaccination is prescribed against (such as that it must be a dangerous contagious disease, etc.). The legislature has therefore left, without setting any conditions, fully to the discretion of the Ministry which diseases (zero, one, nine or even fifteen) the vaccination shall be compulsory against. The very real extent of interference with the right to the inviolability of person is therefore prescribed by the decree and not by law.

11. Further, if balancing the effectiveness of spa treatment and economic viability is to be reserved for political decision-making in the parliament, it is not explained how the balance between the protection of public health and the forced interference with bodily integrity could be left to the executive power. Even more so when there is a greater need for legitimation and a public (and political) debate because it involves an interference with the very fundamental rights which certainly include the protection of bodily integrity.

12. The judgment does not deal at all with the case-law of the Plenum as to *reservatio legis*. The majority has failed to explain why it has departed from the previous case-law and why the case under consideration differs from the previous ones. I do not contest here the power of the Plenum of the Constitutional Court to depart from its previous case-law. However, it must be done only with good reasons and with a careful, detailed, and convincing justification [cf. for example the judgment, file No. Pl. ÚS 11/02, of 11 June 2003 (N 87/30 of the Collection of Judgments of the Constitutional Court 309; 198/2003 Coll.), or the debate in Bobek, M., Kühn, Z. et al. *Judikatura a právní argumentace* (Case-law and Legal Arguments). Issue 2. Prague: Auditorium, 2013, pp. 356 to 363]. I therefore can hardly resist the impression now that the position of the majority to *reservatio legis* is selective and without regard to the express provisions of the Charter of Fundamental Rights and Freedoms. Unfortunately, such decision-making is the opposite of a principled and convincing decision-making, which is the basis of the legitimacy of the judiciary.

13. Ignoring *reservatio legis* as clearly set out in the constitutional text (under Article 7 (1) of the Charter, the inviolability of person may only be limited in the cases specified by law) is then an interference with the separation of powers, since the executive power interferes with the domain of the parliament which alone may limit in the form of law the scope of the fundamental rights and establish a balance between the fundamental right to bodily integrity and the public interest in the protection of public health and the protection of the rights of others. Also Article 4 (2) of the Charter lays down the rule that the limits of fundamental rights may only be

modified by law. On top of that, the vaccination obligation is sanctioned by a penalty and, therefore, imposing this obligation by means of law would also be more conforming with Article 4 (1) of the Charter.

14. In conclusion, I also state that the argument often made that the modification through a decree allows greater flexibility for emergency circumstances cannot stand either. I am convinced that the good legislation which after the proper parliamentary debate creates rules under what circumstances, against what type of disease, and to what extent it is possible to prescribe the vaccination obligation by means of secondary legislation should have a totally different quality of interference with the fundamental rights than the existing blank cheque provided by the contested law to the Minister of Health or to several experts hidden from the public eye in order to create a comprehensive vaccination policy of our country without any democratic and judicial control. In other words, nothing prevents the legislature from adopting a statutory provision which provides for the vaccination obligation for standard circumstances directly in law and allows prescribing the vaccination obligation for emergency circumstances through the secondary legislation within the statutory limits, albeit on a short-term basis. The fact that the legislature has not done so will not however stand as the reason for the determination of all the important aspects of vaccination obligation in the secondary legislation at all times.

4. Violation of the principle of proportionality in determining the obligation

15. Even if the text currently contained in the decree was included in law wholly, even then the text would be constitutionally conforming. The right to the inviolability of person (bodily integrity) under Article 7 (1) of the Charter and Article 8 of the Convention is not an absolute right and it may be interfered with, but only adequately in relation to the legitimate interest pursued. The judgment correctly applies a five-stage test of limiting the fundamental right which is based on the case-law of the ECHR and the Constitutional Court. However, in the last step (comparison of conflicting interests) it omits that the case-law of the Constitutional Court, unlike the ECHR, has a sophisticated algorithm of this step. It is a standard test of proportionality. The necessity of maintaining the proportionality in any interference with the fundamental rights results from the constitutional order (in particular Article 4 of the Charter) and has already been sufficiently defined by the case-law of the Constitutional Court. According to the case-law, any interference with the fundamental rights is proportional to the legitimate interest if it meets the following three criteria [see the judgment, file No. Pl. ÚS 31/13, of 10 July 2014, (162/2014 Coll.), Item 41; the judgment, file No. Pl. ÚS 37/11, of 30 July 2013 (299/2013 Coll.), Item 59; the judgment, file No. Pl. ÚS 24/10, of 22 March 2011 (N 52/60 of the Collection of Judgments of the Constitutional Court 625; 94/2011 Coll.), Item 37; and a number of others]:

- (1) The measures limiting the fundamental right are capable of achieving the objective pursued (test of appropriateness).
- (2) The objective pursued cannot be achieved to the same or similar extent by other means which would interfere less with the fundamental right (test of necessity).
- (3) The interference is adequate, i.e. the seriousness of the interference with the fundamental right is balanced in the specific situation by the importance of the objective pursued, as the sacrifice made in the form of any limitation of fundamental rights must not become disproportionate in relation to the benefits brought by the limitation (proportionality in the narrow sense).

16. It is undisputed that the blanket vaccination against major infectious diseases is important for protecting the public health and the protection of the rights of others. High vaccination coverage helps to create the so-called collective immunity that protects also the persons who cannot be vaccinated against diseases for serious medical reasons or their immunisation by vaccination fails for any other reason. As far as here, I agree with the view of the majority in the application of the five-stage test (Items 74 to 77). However, I cannot identify with the view of the majority as regard the proportionality test for the following reasons.

17. In the first step of the proportionality test, the test of appropriateness, taking into account the available scientific information, I agree that the compulsory vaccination against major infectious diseases is a measure that is capable of protecting the public health and the rights of others.

18. The current legal regulation, however, does not stand in the second step of the proportionality test, the test of necessity, since the objective of protecting the public health and the rights of others could be achieved to a very similar or even the same extent even in a more considerate manner towards the fundamental right to bodily integrity.

19. The current legal regulation and practice does not stand the test of necessity because it determines not only the disease against which a person must be vaccinated but also the type of vaccine that has to be used and even in what dosage it should be administered. Under various sanctions it is therefore prescribed what vaccine must be accepted by the parents without any reservation for the vaccination of their child. While to protect the public

health it is certainly sufficient to establish the disease and the age of the child and until when the child must be vaccinated against the disease, not at what specific times and what combination of vaccines must be used for the child as prescribed within the obligation under the decree. In other words, an alternative solution - the possibility of individual vaccines administered separately according to the individual schedule convenient to an individual child - is capable of achieving the objective pursued (the protection of public health and protection of the rights of others) to a very similar or even the same extent as the existing solutions consisting in the vaccination of hexavaccine at fixed times, and this alternative solution is at the same time more considerate towards the concerned fundamental right to the inviolability of person, which includes the right to be subjected to medical procedures only with one's consent. The more considerate solution would consist in that in addition to the clearly defined obligation a manner would be chosen in order to preserve to the widest possible extent the right to decide on individual modalities of interference with bodily integrity.

20. By analogy, the producer of the compulsory hexavaccine (Infanrix) commonly applied in the Czech Republic itself states that it can be administered either in three doses with one booster administered later, which is a compulsory scheme according to the decree, or in two doses with one booster administered later. Both schemes have practically the same effectiveness as evidenced by the data of the European Medicines Agency (EU institution; see http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000296/WC500032505.pdf, pp. 7 to 8). Maintaining the possibility for the parents to choose between two modalities of the administration of hexavaccine at own discretion is more considerate towards the fundamental right, while being able to achieve the objective pursued to the same extent.

21. For these reasons, the existing legal regulation should be annulled. Since it does not stand already in the second step of the proportionality test, it is not necessary to proceed to the third step of the proportionality test. Even if those deficiencies are remedied in the future, however, the existing legal regulation would be unconstitutional because it would not stand even in the third step of the proportionality test, namely the comparison test. Here it is necessary to decide whether the benefits for the public health and the protection of the rights of others outweigh any interference with the rights of an individual. In this particular case, this means to consider as for each individual disease for which the vaccination obligation is determined the following questions: How is a given disease dangerous, what is the risk of its occurring without the existence of compulsory vaccination, how quickly and easily is the disease communicated (this is a factor with great importance if the objective pursued is to protect the public health and the rights of others), what is the effectiveness of vaccines, and what is the risk of vaccines?

22. The existing legal regulation is, however, generally disproportionate at first due to the fact that, on one hand, it prescribes the obligation to undergo vaccination because of the public interest in protecting the public health but, on the other hand, it does not contain the obligation of the state to be fully responsible for any injury to health caused by the vaccination the person was obliged to undergo on the grounds of public interest. Even the vaccination carried out fully *lege artis* may in certain cases be very detrimental to the health of individuals who are obliged under law to undergo such vaccination. Then, however, it must be made clear that the sacrifice for the sake of public interest, which shows the connection between the injury and the compulsory vaccination, must be compensated under law. Under the existing legal regulation, however, a physician or even a producer of the vaccine are not responsible for the consequences of vaccination carried out *lege artis*; the new Civil Code and the Act on Health Care Services have correctly limited the responsibility for medical procedures causing any injury to health arising from the application of any chemicals, nevertheless in case of negative consequences of vaccination it is a sort of "expropriation" of the health of individual in favour of public interest, which should always be fully compensated. The foreign legislations regulate this explicit liability for that injury as the civil damages in such cases are not applicable since the injury in exceptional (but admitted by experts) cases occurs even while maintaining all obligations, i.e. the injury occurs without it being caused by any illegal step of a health care provider, vaccine producer or the state. For example, the law in force in the USA imposes upon the state the obligation to compensate for any adverse effects of the vaccine, regardless of fault, and even for vaccinations which are merely recommended. The law even recognises the difficulty in proving the causal connection and, therefore, proving the causal connection of the established effects with the vaccination is not required. The table which is part of law enumerates side effects and the time limits since the vaccination within which they must occur. Provided that these conditions are fulfilled, the entitlement to compensation occurs automatically without further evidence (see 42 U.S. Code, Sec. 300A-14). Similar legislation and compensation programs, albeit different in details always based on strict liability, exist in tens of other countries including those where vaccination is only voluntary (e.g. Germany, Austria, Finland, Sweden, Norway, France, Switzerland, Italy, Slovenia, the United Kingdom, etc.).

23. The judgment therefore rightly concludes in Item 87 that the legislation should consider complementing the legal regulation of vaccination by the liability of the state for the negative effects of vaccination. The fact that the existing legal regulation does not ensure such compensation, however, cannot be simply dismissed by mere *obiter dictum*, because it is an integral part of the proportionality of the regulation of vaccination. In other words, if a child has to undergo any compulsory vaccination in the interest of the society, his/her sacrifice must be automatically compensated under law in the case of negative health consequences; only thus the balance between the right to bodily integrity on one hand and the protection of public health and protection of the rights of others on the other hand is maintained. Unless it is explicitly provided for by law that the victim of negative consequences of compulsory vaccination shall always be compensated, then such person must bear excessive (inadequate) burden for the sake of public health. The fact that the possibility of claiming compensation in this situation is part of the assessment of the adequacy of the regulation of compulsory vaccination is also admitted by the case-law of the ECHR (see the decision *Salveti v Italy* of 9 July 2002, No. 42197/98). At the same time, the statutory demand for compensation is based on Article 24 of the Convention on Human Rights and Biomedicine which is part of the constitutional order [judgment, file No. III. ÚS 449/06, of 3 February 2011 (N 10/60 of the Collection of Judgments of the Constitutional Court 97)], according to which a person who has incurred any injury resulting from any procedure shall be entitled to fair compensation under the conditions and procedures prescribed by law. I trust the Czech judiciary that it would perhaps find even without any explicit legal regulation some way how damages could be achieved, but the existing legal regulation (or the lack of such legislation) puts the persons subject to the vaccination obligation to an unacceptable legal position - if the vaccinated child suffers from irreparable health disability, he/she can expect many years of court trials without a clear result.

24. I also note that in the proportionality test of compulsory vaccination it is always necessary to justify very carefully and properly the selection of diseases against which the compulsory vaccination would be prescribed. Even the international comparison shows that the number of diseases against which the vaccination is compulsory in the Czech Republic significantly exceeds the number of diseases against which the need for vaccination is prescribed in other European countries (except for some states to the east of our country). The proportionality test should be performed for each disease separately because the compulsory vaccination against each individual disease is an independent interference with the right to the inviolability of person under Article 7 (1) of the Charter.

25. As an example of the application of the last step of the proportionality test, the blanket vaccination obligation against hepatitis B might be mentioned as for which one can seriously doubt that it is adequate. The disease is communicable only through bodily fluids, i.e. in practice, most often through sexual contact or blood contamination, for example through the use of shared syringes among drug addicts. Although there is a theoretical possibility of communication from the saliva of infected individuals through a strong bite, those cases are very rare or even solitary (Hui, Alex Y. et al. Transmission of hepatitis B by human bite-Confirmation by detection of virus in saliva and full genome sequencing. *Journal of Clinical Virology*, Volume 33, Issue 3, 254 - 256). Its communicability in small children is then very limited. For this reason, any blanket vaccination of infants is capable of attaining the objective of the protection of public health and the protection of the rights of others to a very limited extent. On the other hand, we must take into account the side effects of vaccination against hepatitis B. According to scientific studies submitted by the complainant in their reply, the vaccination against hepatitis B can cause a serious or lifetime disability to seven children statistically every year in the Czech Republic. Comparing the conflicting interests speaks therefore rather against the proportionality of compulsory blanket vaccination against hepatitis B.

26. It is therefore not surprising that before the compulsory vaccination against the disease has been introduced, the expert analysis of the National Health Institute did not recommend the introduction of compulsory vaccination. We do not know for what reason the obligation has been prescribed, which is also the consequence of the fact that the obligation has been determined only by a decree without any public debate in the parliament, explanatory memoranda, etc. In its response to the constitutional complaint, the Government justifies the compulsory vaccination against hepatitis B only by that the risk of serious course of the disease is much higher in the case of small children. This argument, however, relates to the protection of public health to a limited extent only. It primarily concerns the protection of the individual health of an infected person. Although the issue of communicability of disease is much more important in terms of the protection of public health. Under these circumstances, one cannot reach a conclusion on the proportionality of the vaccination obligation against hepatitis B. At the same time, it goes without saying that the legitimacy of an interference with a fundamental right and its adequacy must be proved by the interfering entity, in this case the Ministry of Health.

27. Finally, it should be noted that one of compulsory vaccinations is the vaccination against tetanus which is not communicable from one child to another at all. This vaccination thus does not protect the public health or the rights of others. The reason for the introduction of vaccination obligation in this case it is probably protecting children against the decisions of their parents. This constitutes an interference with family relationships and parental rights (Article 8 of the Convention and Article 10 and 32 of the Charter), without it being subject to political deliberation in the parliament and a decision whether the political majority in our country thinks that the state knows better what is good for children than their parents. The proportionality test would in this case have to be a little stricter with regard to the fact that the rights of parents to make decisions about their children are here against the right of the child provided and protected by the state, the protection of which against other harmful parental interferences is also ensured by traditional liability instruments of public and private law.

28. I note with regret that the majority has not mentioned in the judgment any of the above considerations on the proportionality of the existing regulation of the vaccination obligation. The comparison of conflicting interests made in Items 78 to 84 of the judgment is very superficial and virtually no proportionality test has been performed. The reasoning only refers to the three recommendations of international bodies and the statistics of morbidity decrease for the three diseases after the introduction of blanket vaccination. The statistics are certainly relevant in an analysis of proportionality but refer only to three of the nine diseases and, in addition, only demonstrate the potential effectiveness of vaccination programs, which is however only one factor in the comparison. As to the international recommendations referenced in the reasoning in Items 81 to 83, they refer only to the general appropriateness of vaccination programs. Neither of those documents, however, recommends that the vaccination should be compulsory, or even that the vaccination should be compulsory against nine diseases, as it is in the Czech Republic. With respect to the example of hepatitis B mentioned above, it can also be noted that the vaccination against this disease is mentioned in none of these documents at all. The proportionality of the Czech regulation of compulsory vaccination can be inferred from those documents only to a very small extent, if anything.

29. After all, it cannot be omitted that the case under consideration deals with an interference with the right to the inviolability of person, which is one of the leading fundamental human rights as is mentioned in the judgment (Item 56). As such, it must have a much more rigorous constitutional review than what can be found in this judgment.

5. Summary

30. I find the current Czech legal regulation of the compulsory vaccination in conflict with the fundamental right to the inviolability of person as the extent of compulsory vaccination is entirely left to the discretion of the Ministry of Health and is not determined by law, as required by the Charter. At the same time, the current legal regulation does not even meet the requirement for proportionality of an interference with fundamental rights since the objective pursued (public health) could be achieved to the same extent using more considerate means in which the choice and dosage of the vaccine are left to the parents alone after consultations with physicians; the current legal regulation does not contain the strict liability of the state for any injury to the health of an individual who has undergone the compulsory vaccination; and finally the list of diseases which the compulsory vaccination is prescribed against is excessive since the obligation is not adequately justified by the protection of public health in case of all of them.

31. Unfortunately, the majority of the Constitutional Court rather assessed in this case the quality of health care in the Czech Republic or judged parents who, through their criticism of the existing vaccination obligation, in force in the Czech Republic may expose their own or other children to risks, which is however not the task of the guardian of constitutionality. The Constitutional Court, in my view, has failed to fulfil its obligation to assess, without prejudice and from the perspective of its expertise, the constitutionality of the contested legal regulation, as required in all other cases.

In Brno on 27 January 2015