EUROPEAN COURT OF HUMAN RIGHTS
COUNCIL OF EUROPE
Johan Callewaert
Deputy Grand Chamber Registrar
67075 STRASBOURG CEDEX
FRANCE

24 February 2020

## Observations of applicants

Application no. 47621/13 (Vavřička v. the Czech Republic) Application no. 3867/14 (Novotná v. the Czech Republic) Application no. 73094/14 (Hornych v. the Czech Republic) Application no. 19298/15 (Dubský v. the Czech Republic) Application no. 19306/15 (Brožík v. the Czech Republic) Application no. 43883/15 (Roleček v. the Czech Republic)

## 1. Introduction

At the outset of our observations, we would like to state that we are aware that public health protection will be assessed as a legitimate objective of the State, yet the complaints are intended to point out that the Government treats this objective arbitrarily, repressively and without justifying the necessity of the adopted measures, which at times do not even make elementary logical sense. This system undermines the fair balance between the interest in protecting public health and the fundamental human rights of citizens, which are completely neglected.

We consider the system of mandatory vaccination in the Czech Republic to be inconsistent with a number of articles of the Convention for the Protection of Human Rights and Fundamental Freedoms, due to inadequate, non-transparent and medically unjustified repressive measures, which have been increasing. As a result, these measures are counterproductive and increasingly reduce public confidence in vaccination. They include an arbitrary imposition of any vaccination as mandatory under the threat of a fine and excluding a child from preschool education and some other collective activities.

At the same time, any review, including a judicial review of these measures, is excluded in the Czech Republic, as these are "expert" and "political" issues the justification and proportionality of which the courts refuse to review. This is despite the fact that the Czech vaccination system is demonstrably under the control of a narrow interest group of people who act in a non-transparent manner, some of whom being in an obvious conflict of interest.

The only factual assessments of the adequacy of repressive measures in association with vaccination in the Czech Republic include the dissenting opinions of Constitutional Court Judge Kateřina Šimáčková and the statement of the Public Defender of Rights Anna Šabatová, concluding that these measures are disproportionate. The translations of these opinions and statements are enclosed to these observations.

We do believe that the Court will not be satisfied with the Government's seemingly convincing responses, but that taking into account the seriousness of the rights concerned (in particular, in the case of children, the right to education and the right to the physical integrity as part of their right to private and family life, and in the case of their parents, the right to act in accordance with their conscience), it will carefully assess the issue of the proportionality of the repressive measures, and will also take into consideration the description of situation by reliable parent and patient associations, acting as the so-called amici curiae in the proceedings.

## 2. The Facts

# 2.1. Non-transparent decisions on mandatory vaccination and the absence of analyses on the necessity of mandatory vaccination

## 2.1.1. Observations of the Applicants Roleček and Vavřička of 15 April 2016

The Czech Republic orders mandatory vaccination, which it enforces by sanctions, without having first independent analyses on suitability, need and necessity of this action for every disease subject to vaccination. The government does not have any such analyses and explains mandatory vaccination only by non-reviewable, one-sided opinions by professional corporations, members of which are often in the conflict of interests. We will explain these conflicts of interests and one-sidedness of the government's professional statement in detail further in our statement; here we will comment on the need of analyses preceding the introduction of mandatory vaccination, which affects many rights pertaining to children and their parents.

The League of Human Rights has dealt with the need to justify the vaccination schedule and its modifications in the analysis named "Influence of pharmaceutical companies, vaccination and advertising":

The proposed changes in the immunization schedule should be considered according to certain criteria in order to protect public health and society against the spread of serious infectious diseases and at the same time to protect the individual's health and their personal integrity and other rights, as well as other social interests, such as effective and economically reasonable spending of public money.

Before a vaccination against a certain disease is introduced in the immunization schedule or among regular vaccinations, both its advantages and disadvantages should be assessed on a long-term basis. The available scientific findings should be considered with regard to the society in the given country and to the possible introduction of the vaccination in the existing immunization schedule and its change.

The Finnish National Institute for Health and Welfare looks for answers to the following four questions when considering any change in the national immunization program:<sup>1</sup>

- 1. Will global vaccination improve public health? The answer is influenced by the incidence and seriousness of the given disease, as well as by the degree of protection provided by available vaccines.
- 2. If so, is the vaccine safe on the individual level?
- 3. If so, can there occur adverse effects on the level of public health that would be graver than the benefits?
- 4. If not, are costs and benefits balanced? In other words, what will the balance be between public health and economic benefits on one side and costs associated with the introduction or change of vaccination, including possible risks, on the other side?

As far as these medical technologies are concerned in Denmark, they evaluate the answers to all following five questions:<sup>2</sup>

- 1. Epidemiology (is there a problem?)
- 2. Technology (can one or more vaccines solve the problem?)
- 3. Parents' attitude towards further vaccination (do they want such solution?)
- 4. Organization (can we handle it?)
- 5. Economy (can we afford it?)

In our country there are no officially defined criteria. Yet, introduction of such criteria and properly and publicly given professional reasons for the setting of and changes in the immunization schedule, including recommendations and opinions of the National Advisory Committee on Immunization would lead to a more transparent decision-making concerning these matters and would make such decisions objectively reviewed. So far, these decisions are not or only partly accounted for. Still, this could be done in the argumentative reports on the Public Health Protection Act and the implementing regulation, as well as on the website of the Ministry of Health and in the National Advisory Committee on Immunization section.

An exception, when a comprehensive analysis was drawn up prior to the large-scale implementation of mandatory vaccination in the Czech Republic, was the analysis concerning B-type hepatitis. Although its owners did not recommend the introduction of a large-scale vaccination, the vaccination was introduced, not

<sup>&</sup>lt;sup>1</sup> Örtqvist, Å. Vaccination of children – a systematic review. Acta Pædiatrica ISSN 0803–5253, 99/2010 (Suppl. 461), p. 10.

<sup>&</sup>lt;sup>2</sup> Ibid.

only on a large-scale, but also as mandatory. Again, we can quote the analysis "Influence of pharmaceutical companies, vaccination and advertising":

In 1995 The National Institute of Public Health, managed by Jaroslav Helcl, a respected expert on epidemiology of viral hepatitis, carried out a study entitled "Background materials for strategy on vaccination against Hepatitis B in the Czech Republic". The results of the study showed that in our country the vaccination of high-risk newborns against Hepatitis B produced very good results and that this aimed vaccination, which was introduced, provides a better and cheaper protection of the high-risk group than the global vaccination, and therefore "it is not advisable to introduce regular vaccination of newborns in our country". The results of the study were presented as a background material for decision on further strategy for vaccination against Hepatitis B to the Chief Public Health Officer, a predecessor of Michael Vít. <sup>3</sup>

Although there has been no known subsequent study that would obtain different results, and although the epidemiological situation has not changed either,<sup>4</sup> in 2001 the Ministry introduced compulsory vaccination against Hepatitis B of all children in the first months of their lives. Another vaccination that was introduced for children was vaccination against Haemophilic Influenza B.

The implementation of neither of the aforementioned vaccinations in the immunization schedule has been accounted for neither by an expert nor in public. No studies have been published that would support this action, neither has anyone made any comments on Helcl's study. But most importantly, no reason has been given for the nature of circumstances, which required that the vaccination should be compulsory and that the neglect of this duty should be sanctioned, whereas the vaccination should have been voluntary and covered by the State.

Although the government refers to WHO recommendations, WHO does not prompt countries to introduce mandatory vaccination. WHO recommendations would be fulfilled even if the Czech Republic only recommended vaccination and offered it free of charge, similarly as other countries. That would not affect individual's rights in such an extreme extent as an involuntary and risky intervention into ones physical integrity.

Moreover, from the perspective of conflict of interest, WHO is equally problematic as Czech professional corporation; it is broadly sponsored by pharmaceutical corporations producing vaccines<sup>5</sup>, e. g. by GlaxoSmithKline, which is the main supplier of mandatory vaccines in the Czech Republic and which is engaged in unfair practices, such as false advertising and similar conduct, in the Czech Republic.<sup>6</sup> Therefore, it cannot be logically expected that WHO would enforce a careful approach at vaccination; with regard to the sponsors' interests, it is no wonder that WHO's main aim is "to immunize more people against more diseases", <sup>7</sup>as pointed out by the government (Section 65).

In his application, the applicant Roleček pointed out that according to the public health law doctrine before adopting a regulation on the protection of public health, five steps need to be assessed – risks identification, proof of the effectiveness of the measure, the economic costs, the burden set on the individuals and the fairness of the policy. Assessment of the risks to public health, before adopting a regulation, consist of assessing the probability of injury, its severity, duration of the risk and nature of the risk. Hence an independent assessment of the need for vaccination (through analyses for the particular country) is much more important than the WHO's global policy. Unfortunately, this does not happen at all.

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 $<sup>^3</sup>$  The final report on the grant solution by the Internal Grant Agency of the Ministry of Health of the Czech Republic, No. E/2478-1, the subject committee No. 8, project conceived by: NIPH, time of solution: 1994 – March 1995.

 $<sup>^{\</sup>rm 4}$  Institute of Health Information and Statistics of the Czech Republic.

<sup>&</sup>lt;sup>5</sup> http://www.foxnews.com/projects/pdf/WHO voluntary contributions 2010.pdf

<sup>&</sup>lt;sup>6</sup> For example, the State Institute for Drug Control penalized this company in 2010 for false advertising – source: , the State Institute for Drug Control; information given on 9<sup>th</sup> December 2011, file ref. 145618/2011.

<sup>&</sup>lt;sup>7</sup> http://who.int/immunization/givs/en

To sum it up, the state does not have comprehensive analyses and justifications for every disease subject to mandatory vaccination; despite it had such an analysis drawn up in one instance, it did not respect its conclusions and, contrary to them, introduced mandatory vaccination against B-type hepatitis. From the procedural point of view, this procedure is completely insufficient for ordering a risky intervention into an individual's physical integrity.

Another procedural deficiency is that only a small group of people at the Ministry of Health non-transparently decides on mandatory vaccination; many of the people are in conflicts of interests, as mentioned below. A more detailed description is specified in the analysis "Influence of pharmaceutical companies, vaccination and advertising":

The obligation to have yourself and your children vaccinated is defined in the provision of § 46 and subs. of the Act No. 258/2000 Coll., on the protection of public health. However, this Act does not define the particular diseases against which it is necessary to have vaccination. Nor does it define the manner or the period of time, in which the vaccination should be given. All this is defined only in the implementing regulation – that is in the regulation of the Ministry of Health No. 537/2006 Coll., on vaccination against infectious diseases.

The above-mentioned legal regulations are the reason why the decision-making process concerning vaccination is non transparent and completely at the hands of a small group of people at the Ministry of Health. It is only at the Ministry that the decisions are made about the number of injections, the diseases against which a person has to be vaccinated, the vaccines and the periods of time in which a person has to get vaccinated. The people at the Ministry decide about the existence and extent of such serious intervention in the personal liberty, integrity and parental rights, as is the restriction of a person's right to give a free consent with a potentially harmful intervention.

The issue whether the intervention was in line with the law was commented by the Czech government in Section 128 et al. Although the government tries to argue that, in the case of vaccination in the Czech Republic, it is not an unlimited consideration by an executive body enabling wilful interventions into human rights, this is actually the case. As aforesaid, the Ministry of Health does not have analyses for individual diseases subject to mandatory vaccination, which fact itself implies a wilful conduct. In such situation, it is only the ministry's will whether it orders no mandatory vaccination, or only against one disease, or against 10 diseases. It is not clear and reviewable at all, on which grounds the ministry makes these decisions.

We also need to point out the fact that there is a substantial difference between the police option to stop and search people in public (Gillan and Quinton v. United Kingdom, application no. 4158/05) and the option of ministerial officials to groundlessly order a large-scale risky action and intervention into an individual's physical integrity. Of course, an intervention into physical integrity is much more serious; hence, it is unacceptable that the need for it can be ordered, non-transparently and without a proper justification, by a small group of people at the ministry. In our opinion, there is no substantial difference whether it is an executive action — the application of legislation (also see the body search of people of certain skin colour) or the creation of an implementing regulation by executives and the ordering of a large-scale vaccination not taking into account individual circumstances, including attitudes or philosophical or religious beliefs of the particular people or their parents.

If the government argues that the highest Czech courts found the Czech legislation in line with the constitution (Section 133), it needs to be said that opinions on this issue differ. The Constitutional Court approved the wording; however, its legal opinion is not convincing, as it is contrary to its previous judicature, which fact is pointed out in her opposing statement by the constitutional judge Kateřina Šimáčková, who detailed why the

determination of the scope of mandatory vaccination by a decree (see item 3 of her statement on the Constitutional Court's findings of 27<sup>th</sup> January 2015, file ref. Pl. ÚS 19/14) does not stand.<sup>8</sup>

Moreover, judges' legal opinions on this issue are not unanimous. One of the panel of judges of the Supreme Administrative Court reached a conclusion that the legal regulations do not define any restrictions on the Ministry regulation and therefore the law gives the Ministry an unrestricted space to determine which vaccinations will be compulsory. The Court observed that the particular obligation is in fact defined only in the implementing regulation, and such state is in contradiction with the constitution.<sup>9</sup>

If the government argues that Czech courts have pointed to the fact that the current legislation enables a sufficiently flexible response to the development of the occurrence of infectious diseases and scientific knowledge (Section 134), the Czech practice has shown that it is not true and that the ministry has ignored the pressure by experts from among the public calling for the cancellation of risky vaccination of newborns against tuberculosis for a long time. We can quote the analysis "Influence of pharmaceutical companies, vaccination and advertising":

Global vaccination of newborns against TB in contradiction with experts' opinion

Since 2001 the Ministry of Health and the Chief Public Health Officer have been repeatedly warned by experts about the need for change of vaccination of newborns against tuberculosis because of the death of several babies with inborn immunodeficiency that were due to the vaccination, and because of frequent occurrence of adverse effects leading to disruptions in the immunization schedule. For several years the officials have evaded all repeated official questions put by the Committee of the Czech Society of Allergology and Clinical Immunology who have come up with a solution produced by experts.<sup>10</sup>

The attitude of the Ministry and the Chief Public Health Officer towards the matter of vaccination against tuberculosis has been mainly criticized by Vojtěch Thon, immunologist, who pointed out the documented death of eight children due to this particular improper vaccination. He has been joined in his effort by Deputy Olga Zubová who, on submitting an interpellation, accused Michael Vít of inactivity that led to needless death of several newborn babies and she hinted that Vít was an "exponent of pharmaceutical lobby". Zubová also pointed out that in other countries the vaccination is administered only to high-risk newborns and that it is not recommended to be administered at all in Germany since 1998, and in Austria since 2000.<sup>11</sup>

Despite the differences in the opinions of various experts concerning the necessary change (especially concerning the question whether the vaccination against TB should be completely cancelled or merely postponed until the child is older), all the experts agreed that it is necessary to abolish global vaccination of newborns in maternity hospitals. <sup>12</sup> Nevertheless,

 $\underline{\text{http://www.moravskoslezskenovinky.cz/zpravy.php?} id=8a4b98dc-afe1-102d-9f31-003048330e04\&style=print;}$ 

Article by Vojtěch Thon called "Imunologické principy bezpečného očkování dětí" ("Immunological principles of safe vaccination of children"), in Pediatrie pro praxi, 11(6)/2010. Available at (only in Czech): <a href="http://www.pediatriepropraxi.cz/pdfs/ped/2010/06/01.pdf">http://www.pediatriepropraxi.cz/pdfs/ped/2010/06/01.pdf</a>;

Article by Vojtěch Thon called "Bezpečné očkování nejen proti tuberkulóze" ("Safe vaccination against tuberculosis"), published on 29th April 2010, in Zdravotnické noviny, available at (only in Czech): <a href="http://www.zdn.cz/denni-zpravy/komentare/bezpecne-ockovani-nejen-proti-tuberkuloze-451356">http://www.zdn.cz/denni-zpravy/komentare/bezpecne-ockovani-nejen-proti-tuberkuloze-451356</a>. 

11 lbid.

<sup>8</sup> http://www.usoud.cz/fileadmin/user upload/Tiskova mluvci/Publikovane nalezy/Pl. US 19 14 an.pdf

 $<sup>^{9}</sup>$  Judgement of the Supreme Administrative Court from ref. no. 21 July 2010, 3 Ads 42/2010 – 92.

<sup>&</sup>lt;sup>10</sup> Article called "Zubová interpeluje Juráskovou kvůli TBC očkování" ("Zubová interpellates Jurásková on vaccination against TB"), published on 13th May 2010, available at (only in Czech):

<sup>&</sup>lt;sup>12</sup> Article by representatives of professional associations called "Očkování proti tuberkulose u dětí v České republice" ("Children vaccination against tuberculosis in the Czech Republic"), published in January 2009, available at (only in Czech): <a href="http://www.ockovanideti.cz/aktuality/BCG">http://www.ockovanideti.cz/aktuality/BCG</a> vakcinace 09.htm; Article by representatives of several professional associations called "Očkování dětí proti tuberkulóze v České republice" ("Children vaccination against tuberculosis in the Czech Republic"), in Pediatrie pro praxi, 2009, 10 (3): 166–167, available at (only in Czech): <a href="http://www.solen.sk/index.php?page=pdf">http://www.solen.sk/index.php?page=pdf</a> view&pdf id=3911&magazine id=4;

the Ministry of Health continued its inactivity and maintained the questionable vaccination in the immunization schedule as a compulsory vaccination. The parents of children who would refuse the vaccination could be fined up to 22,000 CZK for their decision.<sup>13</sup>

Global vaccination of newborns against tuberculosis in maternity hospitals was abolished and replaced by selective vaccination of high-risk children only on 1st November 2010. However, this was done only after the matter had been often discussed in the media and the Ministry had been forced to do so by many parties.<sup>14</sup>

...

As it was just mentioned, in the matter of vaccination against tuberculosis the Ministry had for many years refused to hold the necessary objective discussion on serious side effects of the vaccine against tuberculosis and on the changes in the immunization schedule. Moreover it got in contradiction with the Act on free access to information by refusing to provide public information about the criticized vaccination.<sup>15</sup>

## 2.1.2. Request for Information to the Ministry (January 2020)

Prior to drafting this statement on 23 January 2020, we requested the following information from the Ministry of Health as the supreme public health protection body responsible for the vaccination policy (the application enclosed):

- Whether the Ministry of Health has analyses of the medical necessity of introducing a blanket vaccination to protect public health for each infectious disease for which regular vaccination is laid down in the Decree on Vaccination against Infectious Diseases.
- Whether the Ministry of Health has medical necessity analyses for the condition of undergoing regular vaccination for access to pre-school facilities pursuant to Section 50 of the Public Health Protection Act, for each infectious disease against which regular vaccination is stipulated.
- Whether the Ministry of Health has conducted or had an analysis carried out prior to submitting an amendment to the Public Health Protection Act (parliamentary document No. 530/0), in particular the provisions of Section 50, to address the risks posed by the current status for public health protection.
- Whether the Ministry of Health has evidence of documented cases in the last 10 years when a pre-school child who did not undergo scheduled regular vaccination brought the infection to the pre-school facility as the so-called patient zero, i.e. as the first disseminator of the infection subject to regular vaccination.

We also requested the Ministry to provide the above documents and analyses, if available, and for the last question, we requested the information when and where the event occurred, what infection it was, what the age of the

statement by Vojtěch Thon called "Nové očkování proti TBC pomáhá všem dětem" ("New vaccination against TB helps all children"), published on 19th April 2010, in Tribune.cz, available at (only in Czech): <a href="http://www.tribune.cz/clanek/17373-nove-ockovani-proti-tbc-pomaha-vsem-detem">http://www.tribune.cz/clanek/17373-nove-ockovani-proti-tbc-pomaha-vsem-detem</a>; statement by Roman Prymula and Roman Chlíbek called "Ad Nové očkování proti TBC pomáhá všem

dětem" ("Ad New vaccination against TB helps all children"), published on 19th April 2010, available at (only in Czech): <a href="http://www.tribune.cz/clanek/17375-ad-nove-ockovani-proti-tbc-pomaha-vsem-detem">http://www.tribune.cz/clanek/17375-ad-nove-ockovani-proti-tbc-pomaha-vsem-detem</a>;

<sup>&</sup>lt;sup>13</sup> Each parent could have been fined up to 10,000 CZK according to the provision of § 29 para. 1 letter. f) of the Act No. 200 /1990 Coll., on offences, moreover the parents could have been charged to cover the costs of the proceedings up to 1,000 CZK according to the regulation No. 231/1996 Coll.

<sup>14</sup> See previous footnotes.

<sup>&</sup>lt;sup>15</sup> In 2010 the Ministry of Health got a negative nomination in the Access to Information category of the "Open x Closed" competition for the following act – "The Ministry of Health refuses to answer questions concerning the compulsory vaccination of children against TB, which has long been criticized by the expert public for its level of risk". Available at (only in Czech): <a href="http://www.otevrete.cz/hodnoceni-uradu/soutez-otevreno-zavreno/archiv-souteze/2010/nominace-zavreno-pristup-k-informacim-2010-280.html#16">http://www.otevrete.cz/hodnoceni-uradu/soutez-otevreno-zavreno/archiv-souteze/2010/nominace-zavreno-pristup-k-informacim-2010-280.html#16</a>.

disseminator and the infected persons was, and whether the disseminator or the infected sustained any permanent health consequences and which ones or possibly whether death occurred.

The Ministry replied to the questions by letter dated 7 February 2020 (the reply enclosed), stating that "the Ministry does not have the information requested by you". In addition to this brief sentence, at the very end of the letter, the Ministry, without being asked to do so, elaborated on more than one page the arguments that:

- Medicine is based on valid scientific data. When assessing the impact of unvaccinated individuals, it is impossible to proceed from procedures that are medically irrelevant and in conflict with scientific methods of work.
- Due to the relatively high vaccination rate of our population, the health status of the child population has not yet influenced by unvaccinated children, but this may not be the case in the future. The neighbouring countries are considering the introduction of mandatory vaccination, so there is no reason to question the importance of vaccination, as even according to the Constitutional Court, the protection of public health takes precedence over the interests of the individual.
- If a parent uses a pre-school facility for their child, they must comply with the obligations imposed by the State.
- According to the WHO opinion, the refusal of vaccination and the drop in vaccination rates are one of the major threats to public health.
- The amendment to the Public Health Protection Act (No. 258/2000 Coll.) proposes extending the obligation to admit only vaccinated children to other entities in charge of pre-school child care in order to impose the identical obligations on all providers of this service. Furthermore, the amendment proposes that only a general paediatrician may issue the proof of vaccination or contraindication, with regard to the presentation of allegedly biased facts by physicians of other disciplines.

It may be summarised that even after 5-7 years after the present complaints were filed with the European Court of Human Rights, the Ministry does not consider it necessary to have expert and reviewable analyses carried out concerning the medical necessity of mandatory blanket vaccination and the medical necessity of vaccination obligation as a condition to be admitted to kindergarten for each disease which is determined by the decree. At the same time, the Ministry proposes the stricter legal regulation and extending the obligation to admit only properly vaccinated children to other entities, or excluding children who are not properly vaccinated, from other services without having any expert basis to justify this measure before the public. It also needs to be emphasised that the entire Ministry's reply consist only of general or non-reviewable claims without any reference to expert resources.

## 2.1.1. Deciding on vaccination by untrustworthy persons in conflict of interest and excluding critical voices

Not only is the national repressive vaccination policy unjustified by the State in a reviewable and medically substantiated manner, but untrustworthy persons in the conflict of interest are also involved in the decision-making process and, on the contrary, any critical voices are excluded.

Decision-making is entrusted to a small group of people at the Ministry of Health and its affiliated interest organisations; the decision-making process lacks transparency and public and expert discussion, creating a corrupt environment in which it is sufficient to influence a few individuals with the decision-making authority. The decision-making process mainly involves persons with links to vaccine manufacturers or who may be subject to doubt as to whether they act in the interests of children. Using their authority, these persons then

make recommendations which are in the interest of certain vaccine manufacturers, yet frequently problematic in terms of the interest of the vaccinated children.

The information on the activities of persons who have or have had an impact on the vaccination system in the Czech Republic and why they are untrustworthy and in the conflict of interest, as well as the National Immunisation Commission (NIKO), involving their appointees, and their expert companies funded by vaccine manufacturers, is detailed in the enclosed analysis of "Influence of pharmaceutical companies, vaccination and advertising" (especially pp. 12-40).

## 2.1.2. Key information about the leading Czech vaccinologist and current Deputy Minister of Health

In particular, it is necessary to mention a few fundamental facts about the person of vaccinologist Roman Prymula, currently the Deputy Minister of Health for Health Care, who has a significant influence on the vaccination policy in the Czech Republic and undoubtedly participates in the preparation of Government's observations in this case.

In addition to currently serving as the President of the Czech Vaccinology Societyi<sup>16</sup>, Roman Prymula has been the Deputy Minister of Health for Health Care since March 2017. To perform this function, he is supposed to have a security clearance which he does not have, unlike most deputy ministers. The National Security Authority has been examining him for about 10 months, including his income from pharmaceutical companies. Between 2010 and 2014, Prymula earned more than CZK 32 million (approx. EUR 1.3 million) from clinical trial sponsors, in other words from pharmaceutical companies. We enclose a translated article from the Czech news website from January 2020 dealing with this issue.

Prior to joining the ministry, Prymula was director of the University Hospital Hradec Králové from 2009 to 2016. He was removed from this post by the former Minister of Health for concealing information on conflicts of interest and misrepresenting his extensive private activities.

The Minister said that as a director, Prymula decided to purchase pharmaceuticals and medical devices, the suppliers of which also cooperated with his private company Biovomed and he was thus allegedly in a "flagrant conflict of interest". In the first year of its comprehensive existence, Biovomed collected over CZK 41 million (over EUR 1.6 million) from pharmaceutical companies.<sup>17</sup>

According to Zdravotnický deník (Medical Journal), <sup>18</sup> the Biovomed association and later company engaged in research and clinical trials for the biggest pharmaceutical companies: SmithKline Beecham, Wyeth, GSK Biological Rixensaart Belgium, GSK s.r.o., Pfizer, Sanofi Pasteur Lyon France, Baxter Austria, and Novartis. As for the conflict of interests of Roman Prymula, Zdravotnický deník states: "The "science and research" activity reported by Professor Prymula is almost entirely paid for by pharmaceutical companies, which of course supply medicines for hospitals in addition to vaccines. Until today's removal, Roman Prymula served as the Director of the large University Hospital in Hradec Králové, which purchases medicines in the order of hundreds of millions of crowns. As a teacher, he works at the Faculty of Military Health Sciences, which deals with vaccination, among other things. He is the President of the Czech Vaccinology Society, which fundamentally influences the

https://ct24.ceskatelevize.cz/regiony/1833359-nemecek-odvolal-sefa-hradecke-nemocnice-prymulu-kvuli-stretu-zajmu Article: "Conflict of Interests of Director Prymula? Worse than it Seemed", Medical Jounal, 30 June 2016. Available at: https://www.zdravotnickydenik.cz/2016/06/konflikt-zajmu-reditele-prymuly-horsi-nez-se-na-prvni-pohled-zdalo 

18 https://www.zdravotnickydenik.cz/2016/06/konflikt-zajmu-reditele-prymuly-horsi-nez-se-na-prvni-pohled-zdalo

<sup>&</sup>lt;sup>16</sup> https://www.vakcinace.eu/kontakt

<sup>&</sup>lt;sup>17</sup> Article: "Němeček Dismisses Chief of Hradec Hospital Prymula. Owing to Conflict of Interests", Czech Television, 30 June 2016. Available at:

decision-making of the State on vaccination schemes in the Czech Republic. Moreover, according to testimonies of vaccinologists, Professor Prymula almost monopolised the trials of new vaccines in our country, as almost not a single needle is injected without him in this area. He is therefore in a very serious conflict of interest."

Another article of Zdravotnický deník<sup>19</sup> states that the manner Prymula advises pharmaceutical companies and conducts clinical trials for them and the amounts collected by his family-owned company Biovomed raise doubts. The article wonders whether the amounts of approx. 11 million crowns per year represent a reasonable remuneration for the services provided, or whether the pharmaceutical giants GlaxoSmithKline and Sanofi purchase something more from Professor Prymula. The article anonymously quoted experts on vaccinology and pharmaceutical business who mostly agreed that Prymula was a powerful man who has almost a monopoly on clinical vaccine trials in the Czech Republic and who has been at least for the last 10 years in all major discussions and decisions, on vaccination. The concentration of his roles, functions, and thus power and money is deemed unacceptable. The article also states that this case may have a negative impact on the credibility of vaccination. Let us quote one essential paragraph:

"Owing to his erudition and experience and undoubtedly also the influence which he has had as the President of the Czech Vaccinology Society, Roman Prymula has reached the top of the hierarchy in performing clinical vaccine trials in the Czech Republic. According to well-informed sources of Zdravotnický deník, he was more than attractive serving as a central coordinator of studies for pharmaceutical companies, as he was involved in decision-making on the vaccination policy in the Czech Republic. Although he has left the National Immunisation Committee, he continues to serve in the advisory body of the Chief Health Officer. He retained his influence even if he was not strictly necessary as a central coordinator to conduct a specific study and the company could contact physicians who conducted the study directly among their patients. But it was not possible to avoid him, just due to his influence. Yet it was only a matter of time before the concentration of such great influence and the related financial rewards became too much of a problem."

Regarding conducting clinical studies under the leadership of Roman Prymula, it is necessary to mention the ethically and legally problematic trials of the meningococcal vaccine in children approximately ten years ago. The study was carried out with the contribution of CZK 4,500 to parents, which had an undoubtedly motivating effect on the child's involvement in the study and was not a compensation for the actual costs incurred, which is the only lawful compensation. In addition, the risk minimisation requirement was not complied with when conducting the study, as the vaccine was administered to children concurrently with the hexavalent vaccine and pneumococcal vaccination. Even though a complaint was filed with the State Institute for Drug Control owing to the unlawful incentive payments, the Institute remained inactive. More detailed information on this study may also be found in the enclosed analysis "Influence of pharmaceutical companies, vaccination and advertising" (pp. 51-63). Due to the fact that Roman Prymula has conducted a number of studies, it can be assumed that other studies also took place in the inappropriate manner as described; however, more detailed information was not merely released to the public as was the case with the meningococcal vaccine.

Roman Prymula also actively participated in the effort of the State to get rid of the liability for harm caused by mandatory vaccination. In March 2017, coincidently at the time when Prymula joined the Ministry of Health as the Deputy Minister, the first action was brought against the tate for compensation for the damage caused by mandatory vaccination. Specifically, it was a lawsuit filed by a boy who, in infancy, suffered from a permanent paralysis of half of his face, which was evaluated by his attending physicians (from the field of neurology and infectious medicine) as a result of vaccination. In the proceedings, the Defendant (Ministry of

<sup>&</sup>lt;sup>19</sup> Article: "Millions in the Conflict of Interests of Chief Vaccinologist Professor Prymula": <a href="https://www.zdravotnickydenik.cz/2016/06/milliony-ve-viru-konfliktu-zajmu-vrchniho-vakcinologa-profesora-prymuly">https://www.zdravotnickydenik.cz/2016/06/milliony-ve-viru-konfliktu-zajmu-vrchniho-vakcinologa-profesora-prymuly</a>

Health) submitted the statement of its Deputy Minister Roman Prymula as the statement of the President of the Czech Vaccinology Society, in which he excluded the direct causal link between vaccination and facial paralysis. The Ministry denied the objection that Prymula was in a conflict of interest, claiming that Prymula was appointed the Deputy Minister only after drafting the statement in favour of the Ministry. In response to this Prymula's statement, the attending neurologist of the boy claimed that Roman Prymula's conclusions was inconsistent with medical knowledge and referred to both the literature and the package leaflet for the hexavalent vaccine, both admitting paralysis as a rare adverse effect. The action was eventually dismissed for another reason – according to the courts, the current legal regulation does not allow the State to compensate for the damage caused by mandatory vaccination, so the courts did not even deal with the medical aspect of the case.<sup>20</sup>

## 3. As regards the expert context relied on by the Government

In its observations, Government used expert assertions that we consider to be one-sided, therefore we disprove some of them in the attached document. Although we are aware that in the present proceedings an objective truth cannot be found in this way, we can only repeat that it is the task of the Government to present not only one-sided arguments, but a comprehensive and independent analysis showing the necessity to introduce mandatory vaccination for every disease.

#### 4. The Law

## 4.1. Exhaustion of domestic remedies

Court question No. 1: Have Mr Dubský and Mr Brožík exhausted all effective domestic remedies, as required by Article 35 § 1 of the Convention?

Court question No. 2: In particular, have they asserted their rights by way of a cassation appeal and, as and if applicable, a constitutional complaint?

The applications of Mr Dubský and Mr Brožík concern the violation of the right to a fair trial and other rights within court proceedings on an interim measure filed in a timely manner. Within the line of the proceedings seeking the interim measure, both Applicants have exhausted all effective national remedies, including the related constitutional complaint.

Once the Constitutional Court of the Czech Republic dismissed both Applicants' constitutional complaints as manifestly unfounded, both Applicants were excluded from pre-school education in kindergartens, with a virtually permanent effect which could no longer be effectively reversed. It should be noted (and this also follows from the length of the proceedings at the national level for other applicants) that the length of proceedings before national courts reliably ensures that any remedies on the merits of the case would be decided only when the children were already in school age and when they could no longer be admitted to preschool education. Further proceedings and other remedies at the national level could not reverse the fact that the children were definitively excluded from pre-school education and that the courts failed to provide them with timely and effective judicial protection, which could only be provided within the proceedings on the interim measure.

<sup>&</sup>lt;sup>20</sup> Press release of the Human Rights League: "Court Dismissed First Action Against the State for Compensation for Consequences of Vaccination", dated 22 March 2019. Available at: <a href="https://llp.cz/2019/03/soud-zamitl-prvni-zalobu-proti-statu-na-odskodneni-nasledku-ockovani">https://llp.cz/2019/03/soud-zamitl-prvni-zalobu-proti-statu-na-odskodneni-nasledku-ockovani</a>.

Once their complaints were dismissed as inadmissible by the Constitutional Court (conducted within the line of a petition seeking an interim measure), the legal representatives of the minor Applicants decided not to continue the dispute by filing a cassation complaint on the merits of the case. At the time of the dismissal of the constitutional complaints concerning the interim measure, it was certain that both Applicants could not actually be admitted to the kindergarten at the age of 4-6 years and that a decision on the merits of the case would be issued only at the age when they were already attending primary school. The parents consider their right not to continue in a manifestly ineffective litigation, which owing to the length of proceedings, could no longer result in the actual protection of fundamental rights and freedoms of the children and which could, in any manner, no longer reverse the decision of the courts on the interim measure sought, which was the only one to have the capacity to protect the Applicants' rights in a timely manner. Such proceedings would not only fail to lead to the effective protection of children's rights, but in the light of the established case law of the Supreme Administrative Court and the Constitutional Court, it would not provide any hope that the violation of their rights would be concluded retrospectively.

Following the Judgment in the case of Micallef v. Malta (Judgment of the Grand Chamber, 15 October 2009, no. 17056/06, para. 78-85), the case of Applicants Mr Dubský and Mr Brožík concerns a situation in which a decision on an interim measure represents a decision tantamount to a decision on the merits of the claim. In other words, these proceedings decided on the same "civil rights and obligations" ad the decisions had the same resulting long-lasting and permanent effects. Similarly, a defect in the proceedings on the interim measure cannot be remedied at a later stage, namely in the proceedings on the merits, since the prejudice suffered in the meantime became irreversible and with little realistic opportunity to redress the damage caused.

As for the requirement of exhausting the domestic remedies, according to the ECtHR case law referred to in the "Practical Guide on Admissibility Criteria", applicants are not required to exhaust the remedies which are not adequate and effective and which would lead to the proceedings which would be futile or ineffective. If the Government claims that other domestic remedies were effective, i.e. that they were capable of providing redress – offered reasonable prospects of success, then it is up to the Government to prove this claim. The Applicants maintain that it was only the proceedings on the interim measure that could represent an adequate and effective remedy in their case, and it was exhausted by the Applicants, yet the courts failed to provide the Applicants with the protection of their rights in these proceedings.

## 4.1. Violation of Art. 8 of the Convention

Court question No. 3: Do the facts of the present cases come under the scope of the right to respect for private and/or family life within the meaning of Article 8 of the Convention?

The current issue of the imposed medical procedure and the related application of sanctions undoubtedly fall within the scope of Art. 8 of the Convention. The essence of this right consists in the negative concept of freedom, i.e. "being left alone", 21 thus the existence of a certain private sphere which includes the individual's decision how to live their life and which is not supposed to be interfered with by anyone.

The Court has repeatedly pointed out that concept of private life is a broad term, which embraces, inter alia, the right to personal autonomy and personal development (see Pretty v. the United Kingdom, no. 2346/02, § 61, ECHR 2002-III) and to physical and psychological integrity (see Tysiąc v. Poland, no. 5410/03, § 107, ECHR

<sup>&</sup>lt;sup>21</sup> Gormley. K. One Hundred Years of Privacy. Wisconsin Law Review, 1992, p. 1339.

2007-I; A, B and C v. Ireland [GC], no. 25579/05, § 214, ECHR 2010; and Haas v. Switzerland, no. 31322/07, § 50, ECHR 2011).

The concept of private life also includes the right to live a traditional way of life as part of the right to self-determination (Chapman v. the United Kingdom, no. 27238/95, 18 January 2001).

The Applicants therefore believe that the question of autonomy in decision-making concerning the health of the individual as well as health of their children (including the question whether to get the children vaccinated or not, and against which diseases) falls within the scope of Article 8. By the indirect sanction – restraining of the access to pre-school education for children who did not undergo all of the mandatory vaccinations – the State interferes with the right to respect for private life and with the autonomy of making decisions about medical treatment or its scope. The State thus forces parents to let their children undergo medical treatment which is potentially risky and which may cause and also causes serious damage to their health or even death and what is more – without any compensation from the State.

Court question No. 4: If the previous question is to be answered in the affirmative, did the decision

- a) to fine Mr Vavřička
- b) not to admit Ms Novotná, Mr Hornych, Mr Dubský and Mr Brožík to the nursery school

amount to an interference with their right to respect for their private life and/or family life under Article 8 of the Convention?

The legislation and the procedure adopted by public authorities interfered with the right of all Applicants, as protected by Art. 8 of the Convention.

#### Applicant Vavřička

In the case of Applicant Vavřička, the interference of the State resulted in the financial and other impact. The Government claims that the Applicant has not suffered any significant disadvantage under Art. 35 (3) (b) of the Convention, yet we do not agree with this.

As regards the financial impact, the Applicant was fined CZK 3,000 in 2003 and was obliged to pay the costs of CZK 500 (a total of around EUR 110 following the then exchange rate) for not having his children vaccinated according to the national vaccination schedule. The Applicant pointed out in the application that this amount represented more than half of the minimum monthly wage at the material time.<sup>22</sup> In his earlier response to the Government, the Applicant further objects that at the time when the offence was heard, he was indigent and without any income, registered at the Labour Office and in the divorce proceedings. In his situation at that time, he could not afford to pay a fine. He did not even have money for a lawyer, and therefore the Supreme Administrative Court appointed a lawyer free of charge for him, which clearly shows that the Applicant actually was in a difficult economic situation. In addition, at that time the amount of the fine was half of the minimum monthly wage, to which the applicant referred in his application. It was a considerable sum in his situation.

In addition to the financial disadvantage suffered by the Applicant, non-pecuniary damage also occurred. At that time, the parents were in substantial legal uncertainty about the public authorities' procedure in the case of failure to have children vaccinated. It was common for authorities to put undue pressure on parents and threatened them with the removal of the children and their placement in institutional care, as indicated by

<sup>&</sup>lt;sup>22</sup> Se the website of the Ministry of Labour and Social Affairs: <a href="https://www.mpsv.cz/prehled-o-vyvoji-castek-minimalni-mzdy">https://www.mpsv.cz/prehled-o-vyvoji-castek-minimalni-mzdy</a>.

the findings of the Public Defender of Rights.<sup>23</sup> In this situation, the Applicant was concerned about communication with the authorities and the possible removal of the children. Equally, he suffered damage due to the pressure of the State to act contrary to his conscience and regardless of the opinion of his minor but sufficiently mature children to comment on the vaccination. This situation severely interfered with the Applicant's private and family life, jeopardised the interests of his children as enshrined in the Convention on the Rights of the Child and constituted a substantial emotional distress, significantly exceeding the financial disadvantage.

#### Other Applicants

In the case of the Applicants who were denied access to the nursery school, this interference significantly affected not only the Applicants but also their entire families. As regards the issue of denying access to education, this is further elaborated in the section on the right to education. However, it may be briefly summarised that the denial of pre-school education puts children at a disadvantage in further education and prevents them from joining the children's collective and thus acquiring psychosocial competences. As regards the impact on the private and family life of the Applicants and their families, denial of access to the nursery school negatively affects the entire family, both financially and socially. As it is necessary to provide all-day child care, one of the parents (most frequently in the Czech Republic, the mother) cannot return to work and thus the standard of living of the entire family is reduced compared to other families. This leads to social isolation not only of the children (Applicants) but also of their mothers. The non-admission of a child to a kindergarten thus represents a significant interference with the life of families in comparison with the common practice of families in the Czech Republic. Families are marginalised and parents are faced with a difficult choice.

In addition, the interference with the rights of the children consisted in the fact that they were exposed to the risk that, as a result of the formally prescribed vaccination obligation and the State's pressure, they would undergo a potentially risky procedure, namely:

- Without any assessment as to whether this is in their best interests under the Convention on the Rights of the Child;
- Without the free and informed consent of their parents under the Convention on Human Rights and Biomedicine, and contrary to their parents' best belief and conscience;
- Without the State being liable for the damage caused by vaccination.

All the above interfered with the Applicants' right to private and family life under Art. 8 of the Convention, but also with other related rights, such as the right to health and the right of the child to have all the actions and decisions concerning them in their best interest.

Court question No. 5: If so, did this interference meet the requirements of the second paragraph of that Article?

The wording of the second paragraph reads: "There shall be no interference by a public authority with the exercise of this right except such as is in accordance with the law and is necessary in a democratic society in the interests of national security, public safety or the economic well-being of the country, for the prevention

<sup>&</sup>lt;sup>23</sup> See the 2003 and 2004 annual reports. Available at:

of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others."

Due to the fact that there was the interference with the Applicants' right protected by Art. 8, the following questions need to be answered:

- a) Whether the interference is lawful (question of legality);
- b) Whether it pursues a legitimate objective (question of legitimacy);
- c) And whether it is necessary in a democratic society, i.e. whether the interference is proportionate to the purpose pursued (the question of proportionality).

Questions (a) and (c) are raised separately by the Court, so we will only address the question of the legitimate objective.

The Government argues by the protection of public health along with the protection of the rights and freedoms of others. Briefly, we would like to note that if these were the Government's objectives, the Government would surely have a transparent medical analysis carried out on each mandatorily vaccinated disease which would, inter alia, address the proportion of the benefits and risks of vaccination. As mentioned above, the State had a similar analysis carried out in the past for the blanket hepatitis B vaccination and the result of the expert evaluation did not recommend blanket vaccination, yet it was introduced but not for the benefit of human health but on the contrary, at the expense of their health. Similarly, the Government has no analyses addressing the risks of joint pre-school attendance of children for each of the mandatorily vaccinated diseases. Denying access to pre-school education for children who are not completely vaccinated is based solely on the formal condition of admission by all mandatory vaccinations without a actually examining the associated risks.

As regards the Government's claim that mandatory vaccination contributes to the protection of health, not only public but individual, it needs to be noted that although the Convention for the Protection of Human Rights and Fundamental Freedoms mentions health protection as a legitimate reason, the Czech Republic has also ratified the Convention on Human Rights and Biomedicine, which does not allow the protection of individual health as an exception to the right to informed consent. In its Art. 26, the Convention on Human Rights and Biomedicine admits the restriction only in the interest of the protection of public heath, rather than individual health. If refusal of medical treatment does not jeopardise other persons, it is not permissible under this Convention to restrict their right to free and informed consent. In the case of some mandatorily vaccinated diseases in the Czech Republic, the right to informed consent is restricted contrary to the Convention on Human Rights and Biomedicine. For example, by not vaccinating against tetanus, there is no threat to public health. It is unacceptable for the Government to invoke the possibility of violating the Convention on Human Rights and Biomedicine, which it undertook to follow and which is the only specialised convention in the field of human rights in healthcare. Any other general Government obligations invoked by the Government (right to life under Art. 2 of the Convention for the Protection of Human Rights and Fundamental Freedoms, the International Covenant on Economic, Social and Cultural Rights, etc.) must be interpreted in accordance with the specialised Convention on Human Rights and Biomedicine.

In addition, if the Government had indeed intended to protect individual health, it would not have ignored the issue of compensation for the harm caused by mandatory vaccination for a long time. Although the Government drafted a bill after a long time, it has not yet been adopted. On the other hand, in the case of introducing further repression against families who do not have their children vaccinated according to the official vaccination calendar, the Government is very quick and comes up with new proposals almost immediately and without any public and expert discussion. In addition, we recall the case of a boy who suffered

permanent paralysis of a half of his face as a result of mandatory vaccination and whose application for compensation was dismissed by the Ministry of Health in 2016 and the courts failed to provide any protection, either. The bill on the compensation for damage will not apply to this boy.

The above unambiguously indicates that the claimed objective of protecting public health has not been achieved for all vaccinations imposed by the State and that the objective of protecting individual health is contrary to the restrictions prescribed by the Convention on Human Rights and Biomedicine. In the case of both Government's objectives, there is a lack of any transparent and reviewable expert assessment.

Court question No. 6: In particular, was

- (i) The decision to fine Mr Vavřička and
- (ii) The decision not to admit Ms Novotná, Mr Hornych, Mr Dubský and Mr Brožík to the nursery school

in accordance with the "law" within the meaning of Article 8 § 2 of the Convention?

These decisions were not in accordance with the law within the meaning of Art. 8 (2) of the Convention.

The Government argues that the extent of mandatory vaccination is determined by a decree of the Ministry and not by law, yet the Court interprets the term "law" in the material rather than formal meaning, therefore this term also includes regulations of lower legal force adopted on the basis of the legislature's authority. The Government also claims that the Ministry does not have "unlimited discretion" in determining the extent of mandatory vaccination by means of the decree and cannot commit arbitrariness and discrimination.

We disagree with the Government's position, as firstly the form of the law, rather than a mere decree, is required by Czech law itself. And secondly, the Czech legal regulation fails to comply with the requirements of predictability and fails to provide sufficient guarantees against arbitrary application of the law.

We agree with the Government that, according to the case law of the Court, the term "law" is interpreted as any form of national legal regulations. However, we do not consider it compatible with the Convention if, for good reasons, the State itself imposes stricter requirements (the form of law, rather than a mere decree) on its national legislation, which it then arbitrarily disregards and ignores.

The national law, in particular the Charter of Fundamental Rights and Freedoms, provides as follows:

- Art. 4 (1): Duties may be imposed only on the basis, and within the bounds, of law, and only while respecting the fundamental rights and freedoms.
- Art. 4 (2): Limitations may be placed upon the fundamental rights and freedoms only by law and under the conditions prescribed in this Charter of Fundamental Rights and Freedoms .

Under these provisions and established case law, it is inadmissible that fundamental human rights be restricted and that obligations and their scope be imposed on the basis of a mere decree.

For example, the Constitutional Court, in its plenary Judgment of 10 July 1996, file reference Pl. ÚS 35/95, states as follows:

"As stated above, citizens are entitled to free health care and medical aids on the basis of public insurance and under conditions stipulated in further detail by law. Therefore, if these conditions may only be regulated by law, it is absolutely necessary that the scope and manner of their provision be

defined within the same legislative regime. Any other regulation than by law would constitute the violation of the Charter and thus the constitutionality.

It is not acceptable that the definition of the scope of the volume of healthcare provided for full or partial reimbursement be left to the regulation provided by other than statutory legal regulations. This would place the sphere of protection of fundamental rights and freedoms under the authority of the executive power which is not entitled to such powers."

In other words: if the limitation of a fundamental right (in the case of the Applicants, the right to the inviolability of the person and physical integrity, the right to free and informed consent, the right to education, the right to private and family life, and the right to freedom of conscience) may only be regulated by law, it is absolutely essential that the scope of this limitation be also defined by the same legislative regime. It is not permissible for the definition of the scope of the obligation to undergo vaccination to be left to a mere decree. This would place the sphere of the protection of fundamental rights and freedoms under the authority of the executive power which is not entitled to such powers.

In another Judgment of the Constitutional Court of 20 June 2013, file reference Pl. ÚS 36/11, it is concluded that the reason for the regulation in Art. 4 (2) of the Charter of Fundamental Rights and Freedoms "consists in preventing the executive power from realising its own ideas about how and how much fundamental rights can be restricted. By granting this authority to a democratically legitimised parliament, it is intended to ensure that the restriction of fundamental rights takes place only after a democratic parliamentary debate and, in addition, the restriction of the fundamental right is provided with the subsequent democratic feedback." The Constitutional Court concluded that the essential defining features of a right or obligation must be primarily defined by law. If a defining feature to which the obligation is bound was stipulated in the by-law regulation itself without any support in the law, then the legal regulation is contrary to Art. 4 (1) of the Charter.

In addition, the Judgment of 30 June 2004, file reference Pl.ÚS 23/02, set aside the legal regulation on the grounds that "it constitutes an unacceptable delegation of creating norms to the executive body (Ministry of Labour and Social Affairs) and allow the regulation of the limitations of fundamental rights and freedoms by a by-law. The provisions of Art. 79 (3) of the Constitution authorises ministries to issue legal regulations only on the basis of and within the limits of the law. The contested provisions of the Act are contrary to this article of the Constitution, as the Ministry is authorised to adopt regulation concerning something for which the Act itself does not impose any limits, what it does not regulate at all." According to the Constitutional Court, "the Act, by its conciseness and uncertainty, fails to provide the necessary basic framework for the aforementioned by-law". The Constitutional Court concludes that if the Parliament resigns from stipulating the limits and authorises the executive power to determine what the law is, what the rights and duties of persons are, then it violates constitutional principles.

Another judgment of the Constitutional Court of 14 February 2001, file reference Pl. ÚS 45/2000, explains the meaning of the reservation of the law: "The barriers of matters reserved for regulation only by law protects against the excess of the executive power (the so-called reservation of the law)."

It is therefore contrary to national law and the established case law of the Constitutional Court to entrust the Ministry with decision-making on such a fundamental issue as the extent of mandatory vaccination, which also has consequences for administrative punishment and for the child's access to pre-school education. One of the Chambers of the Supreme Administrative Court first correctly identified this constitutional defect and declared the legal regulation unconstitutional, yet later the Extended Chamber of the Supreme Administrative Court changed its position without any convincing arguments, subsequently being supported by the Constitutional Court. The reason was merely the ideological attitude of the majority of the judges, as it

concerned the issue of mandatory vaccination, which they were reluctant to question. It may be said that as far as vaccination is concerned, the legal principles which otherwise apply in the Czech Republic are suddenly put aside.

The Applicants' second objection to the Czech legal regulation consists in the fact is that it fails to comply with the basic requirements for the quality of the law, namely the requirement for predictability of the law and the requirement for sufficient safeguards against any arbitrary application of the law.

According to the Judgment in the case of Gorzelik v. Poland (no. 44158/98, 17 February 2004), the law is supposed to be formulated with sufficient precision to enable – if need be, with appropriate advice – to foresee, to a degree that is reasonable in the circumstances, the consequences which a given action may entail and to regulate the specific conduct. In other words, individuals must be provided with a reasonable opportunity to deduce from the legal rules how they should behave in order to respect the law.

This condition has not been complied with in the Czech legal order, as the Constitutional Court has gradually inferred the exemptions from the mandatory vaccination on the basis of the right to freely express the religion and the right to freedom of thought, conscience and religion as guaranteed by the Charter of Fundamental Rights and Freedoms. However, in the Applicants' cases, there was no legal certainty and predictability regarding the extent to which this exemption could be applied.

In the case of the Applicant Vavřička, the Constitutional Court formulated a religious exception for the first time (Judgment of 8 February 2011, file reference III. ÚS 449/06). The Constitutional Court asked a question whether it was constitutionally conforming to enforce mandatory vaccination against any person, regardless of the individual particularities of the case and the person's motivation of the decision not to undergo mandatory vaccination. The Constitutional Court responded to this question by saying that the constitutionally guaranteed right to manifest one's religion or belief and the associated protection of individual autonomy requires that mandatory vaccination not be enforced against obliged entities in exceptional cases. The Constitutional Court also referred to amicus curiae opinion of the Committee on Human Rights and Biomedicine of the Council of the Government of the Czech Republic for Human Rights, according to which the exceptional non-enforcement of vaccination cannot jeopardise the constitutionally protected interest in the protection of public health. The Constitutional Court stated: "In the event that there are such circumstances that fundamentally call for the person's autonomy to be maintained, while at the same time maintaining the contrary public interest (see, for example, the consequences of the "vaccination rate" as interpreted above), and thus for exceptionally not imposing sanctions due to the obligation to undergo vaccination, the public authority must not penalise or otherwise enforce the above obligation to undergo vaccination."

In addition, in its Judgment, the Constitutional Court elaborated on the criteria for deciding on an exemption: (1) the urgency provided by the person's alleged reasons for non-vaccination; (2) the constitutional relevance of these reasons; (3) threat to society; (4) the consistency and persuasiveness of the claim of the person; and (5) the interest of the minor. At the same time, the Constitutional Court found that the application of these criteria to the situation of the Applicant Vavřička appears that, in particular, the conditions for the consistency of his position had not been complied with in this case, since the complainant began to explain his position by constitutionally relevant reasons at a relatively late stage of the administrative proceedings. The Constitutional Court stated that once the case was referred back to the Supreme Administrative Court, it would be up to the Supreme Administrative Court to review the case again according to the criteria set by the Constitutional Court's decision. As stated in the Mr Vavřička's application, the Supreme Administrative Court subsequently assessed the case as not complying with the criteria of the Constitutional Court (Judgment of the Supreme Administrative Court of 30 September 2011, file reference 5 As 17/2005-120), and the subsequent

constitutional complaint of Mr Vavřička was dismissed as inadmissible by the Constitutional Court (Resolution of the Constitutional Court of 24 January 2013, file reference III. ÚS 271/12).

The reasons why Mr Vavřička did not communicate with the administrative authority from the outset and did not explain his position as required by the Constitutional Court are explained in this observation concerning the Court question No. 4. The Applicant was concerned about communicating with the authorities due to the possible removal of the children, and at that time he was not at all aware that he could and should make any reservation for religious or conscience reasons. There was no statutory or case-law basis for raising any such objection. It is obvious that in the case of Mr Vavřička, the requirement for the quality of the law was not complied with, namely the predictability of the law, as at the time of committing the alleged infraction, he could not assume that the Constitutional Court would infer any criteria for exemptions from mandatory vaccination. However, if the Applicant had been aware of these criteria from the outset, he could have proceeded to comply with them. Thus, the State made an inadmissible retroactive interpretation of the law to the detriment of the Applicant, in particular in imposing administrative sanctions, which is supposed to follow the principles of "nulla poena sine lege certa" and "nulla poena sine lege scripta". This procedure adopted by the State violated the Applicant's right to a fair trial.

In addition to the aforementioned decision of the Constitutional Court in the case of Mr Vavřička, the Constitutional Court in one of its other decisions interpreted the possibility of an exemption from mandatory vaccination, this time based on freedom of thought and conscience (the Judgement of the Constitutional Court of 22 December 2015, file reference I. ÚS 1253/14). This decision did not concern either of the Applicants; the parties involved other persons. In this decision, the Constitutional Court adopted the conclusions of the previous decision, including the criteria for the possibility of an exemption, yet in this case it did not find a violation of the right to express religion and faith but a violation of the right to freedom of conscience. The Constitutional Court found as an expression of freedom of conscience a manifestation of the will or decision of the individual perceived as a personal experience of unconditional duty, a decision dictated by conscience, which cannot be confused with freedom of religion and faith. The Constitutional Court also elaborated on the exemption criteria set out in a previous decision on a religious exemption. As for the criterion of the urgency of the grounds for refusal of vaccination, it stated that the urgency of the reasons alleged in the context of the reservation of conscience against mandatory vaccination remained undoubtedly subjective. According to the Constitutional Court, these objections, which prevent unquestionable compliance with the law, "undoubtedly include the belief that the health of a close person may be irreversibly damaged".

Although the aforementioned criteria for a constitutional law exemption from mandatory vaccination were interpreted by the Constitutional Court some 9 years ago (religious reservation) and 5 years ago (reservation of conscience), there has not been a single case in which the Regional Public Health Offices or the Ministry of Health as the appellate body recognised an exemption against any such penalty.

On the contrary, there have been a number of cases where the authorities refused to recognise the exemption, although it was clearly well-founded. For example, in January 2020, a mother from Brno was fined despite a reservation of conscience based on ethical (vegetarianism and rejection of animal vaccine components and animal vaccine testing), as well as health reasons (strong eczema of the child and worries about its worsening).<sup>24</sup>

As regards the application of exceptions to mandatory vaccination in the case of admitting children to preschool education, the Constitutional Court did not expressly comment on this possibility in the afore-

 $<sup>^{24}</sup>$  Decision of the Regional Health Office of the South Moravian Region of 14 January 2020, file reference KHSJM 02078/2020/BM/PRAV.

mentioned decisions. However, it stated in both decisions that, if the established criteria have been complied with, "the public authority must not sanction or otherwise enforce the vaccination obligation."

In rare cases, the possibility of an exemption also applied to the admission procedure to pre-school education and several children were admitted to pre-school education on the basis of the exercise of the constitutionally guaranteed parents' right to freedom of conscience and the child's right to education without discrimination, <sup>25</sup> yet the Supreme Administrative Court does not admit this possibility.

The fact that the courts allow an exception in the case of administrative sanctions but not in the case of admitting a child to pre-school education does not make sense and constitutes an arbitrary application of the law. If all the criteria of the Constitutional Court for granting exemption have been complied with, including the fact that the admission of a child who is not properly vaccinated to pre-school education does not endanger public health (especially due to a sufficiently high vaccination rate in the nursery school), then there is no reason not to apply the exemption to the admission of children to pre-school education. However, no one examines compliance with the exemption criteria for the admission of children to pre-school education. This indicates insufficient guarantees against arbitrary application of the law. If a constitutional exception to mandatory vaccination is inferred, then it should apply to all forms of sanctions and enforcement of the vaccination, including indirect sanctions in the form of denial of pre-school education to a child.

Failure to comply with the guarantees due to arbitrary application of the law also means that the Ministry of Health has unrestricted discretion to impose any vaccination by decree as mandatory and at the same time it is a body enforcing vaccination through sanctions, therefore it combines legislative and executive functions. Since the Czech courts refuse to review the rationality and adequacy of mandatory vaccination, the Ministry has unlimited power in this area to impose limitations on fundamental human rights and freedoms. The Ministry imposes these limitations without any medical analyses which would be reviewable and without any public expert discussion. On the contrary, untrustworthy persons in the conflict of interest are involved in the decision-making by the Ministry.

The Government claims that when adopting legislation, the Ministry of Health must adhere to the general limits of the Public Health Protection Act, which include: the assessment of health risks arising from natural, living and working conditions and manner of life, current scientific knowledge, international obligations of the Czech Republic in this area, and recommendations of the World Health Organization. It should be noted, first of all, that these "limits" are too general, unspecific and unpredictable. Secondly, the Ministry of Health does not carry out any reviewable analyses to assess the compliance with these conditions, as has been well known in the long term and as has been shown by the recent response to our request for information. And thirdly, as far as the recommendations of the World Health Organization are concerned, it recommends virtually every vaccination, including vaccination against absolutely trivial diseases such as chickenpox. General recommendations of the World Health Organization cannot replace national expert assessments. It should also be recalled that in the event that the national expert assessment took place with a non-recommending conclusion for the introduction of blanket vaccination against hepatitis B, the Ministry failed to respect this conclusion despite that and introduced the vaccination not only as blanket but also as mandatory. All this demonstrates that the Ministry has been abusing its discretion.

Regarding the Government's assertion that the specific form of the decree of the Ministry of Health may and has been repeatedly reviewed by national courts, we note that it is only a formal review without a genuine

<sup>&</sup>lt;sup>25</sup> For example: Decision of the Regional Court in Hradec Králové of 18 January 2012, file reference 52 A 45/2011. Decision of the Regional Authority of the Plzeň Region of 29 May 2014, file reference ZN/878/ŠMS/14.

<sup>&</sup>lt;sup>26</sup> https://www.who.int/immunization/diseases/varicella/en.

substantive review of the rationality and proportionality of mandatory vaccination and without reviewing whether the Ministry oversteps its authority. Indeed, the courts refuse to examine these questions and refuse to test any evidence on the pretext that this is a purely political and expert issue. Thus, in the Czech Republic, it is not possible to seek an effective judicial review of mandatory vaccination and its scope and conditions, even if it does not make the slightest medical sense and even if the vaccination is demonstrably more harmful than good for health. Nor is it possible to carry out a substantive examination of the scope of mandatory vaccinations, which are a precondition for the child's admission to the nursery school, even if the vaccination in question does not in any manner protect the health of the other children in the group. At the same time, the protection of the health of other children is an alleged reason for the Government to make children's access to pre-school education conditional on mandatory vaccination. Thus, for example, the courts tolerate tetanus vaccination as a mandatory condition for admitting a child to pre-school education, even if child-to-child transmission is excluded for this disease, so obviously it cannot be the case of fulfilling the claimed purpose of protecting the health of other children.

Regarding this, we quote both the approach of the Supreme Administrative Court and the Constitutional Court:

Judgment of the Constitutional Court of 8 February 2011, file reference III. ÚS 449/06:

- "The legislature's decision to make a particular type of vaccination mandatory is a decision which implements the possibility explicitly provided for in Article 26 of the Convention. It is a decision which constitutes primarily a political and expert issue, and therefore there is a very limited possibility of the Constitutional Court's intervention. In relation to the quoted Convention, any such legislature's decision enjoys a relatively extensive margin of political appreciation, within which it is impossible to review the legislature's decision on determining the obligation to undergo a certain type of vaccination (or the implementing regulation of the executive power, the so-called margin of appreciation). The Constitutional Court is a judicial body for the protection of constitutionality, and its decision cannot in principle replace the conclusion of the legislature or the executive power that certain infectious diseases require mandatory vaccination."

Judgment of the Constitutional Court of 27 January 2015, file reference Pl. ÚS 19/14:

- "It is not the role of the Constitutional Court to address the question of whether or not the epidemiological situation in one or another country on the European continent justifies the regulation of mandatory vaccination. Although it is possible to make use of expert knowledge in this case, the assessment of these sources belongs to the legislative and executive dispositions."
- "... Determining detailed rules for mandatory vaccination, based on expert knowledge, is supposed to be left to the executive power and conceptual considerations of the legislative policy, even in the event of their impact on individual circumstances."

Judgment of the Supreme Administrative Court of 29 June 2017, file reference 5 As 317/2016-36:

- "In addition, it is not the task of administrative courts to generally assess the auditability of the legal regulation as a consequence of which it will be impossible to admit a non-vaccinated child aged 3 4 years to the nursery school, while the same facility will admit children aged 5 years who are no longer required to undergo the vaccination. (...) In this respect, this is an appeal to the legislature, not to the judiciary, since it cannot a priori answer those expert and political questions."
- "It is the task of the Supreme Administrative Court to assess questions of a medical nature."

"The Supreme Administrative Court emphasises that it is not entitled to assess whether or not the epidemiological situation in the Czech Republic justifies the regulation of mandatory vaccination; whether it should be the right of each individual to decide freely whether he or she or the child granted to their custody is vaccinated. This is primarily the task of the legislative and executive power in the State, being an expert and political issue."

Both courts have consistently refused to address in any manner the substantive review of the mandatory vaccination details, refuse to address the evidence submitted by the Applicants, refuse to test evidence to assess the adequacy of mandatory vaccination for each of the mandatorily vaccinated diseases, and refuse to deal with the Applicants' arguments. The courts have completely resigned from their task of providing the Applicants with judicial protection in their situation, as they do not at all consider whether it is the case of an arbitrary and disproportionate interference with the Applicants' rights or not. Judicial decision-making is based solely on the ideological consideration that vaccination is a measure to protect public health and therefore the State may limit the Applicants' rights at its discretion in order to protect public health.

Within their formal review, despite the Applicants' objections, the courts have failed to address the following issues at all:

- Non-transparent decision-making on vaccination by a small group of persons at the Ministry of Health, some of whom are in an enormous conflict of interests;
- Unlimited discretion of the Ministry in determining the scope of mandatory vaccination and thus determining the conditions for the exclusion of children from pre-school education;
- The absence of any analyses of the medical necessity of mandatory vaccination for each of the diseases and of the medical necessity of the condition of each mandatory vaccination for the purposes of the child's access to the nursery school.

The only factual assessments of the adequacy of repressive measures in association with vaccination in the Czech Republic include the dissenting opinions of Constitutional Court Judge Kateřina Šimáčková and the statement of the Public Defender of Rights Anna Šabatová, concluding that these measures are disproportionate. The translations of these opinions and statements are enclosed to these observations.

In conclusion of this section, we state that for the reasons specified above (failure to comply with the form of the law as required by Czech law, the unpredictability of the law, and the insufficient guarantees against arbitrary application), the interference with the Applicants' rights fails to pass the legality test.

Court question No. 7: Moreover, was the decision referred to in question 6 above necessary in a democratic society within the meaning of Article 8 § 2 of the Convention (see also *Solomakhin v. Ukraine*, no. 24429/03, 15 March 2012), having regard in particular to:

- (i) The seriousness and the impact of the given failure to have the children vaccinated according to the prescribed plan,
- (ii) The scope of the exceptions to the duty to have them vaccinated, in so far as relevant in the given case
- (iii) The way in which the scope of the compulsory vaccination as applicable at the relevant time had been defined,
- (iv) The fact that there appears to be no duty for the nursery schools' personnel to be vaccinated,

- (v) The fact that no provision appears to have been made for compensation in respect of possible health damage resulting from compulsory vaccination (compare and contrast, *Baytüre and Others v. Turkey* ((dec.), no. 3270/09, § 30),
- (vi) In the case of Mr Vavřička, the fact that exceptions to the applicable rules allegedly have only been provided for retrospectively by the domestic courts, and
- (vii) In the case of Ms Novotná, the fact that at the time of the decision not to admit her to the nursery school she had already been in fact attending it?

As regards the issue of necessity in a democratic society, the decision to impose a fine on Mr Vavrička and the decision not to admit other Applicants to pre-school education was not proportionate and not at all necessary in a democratic society.

In this respect, we fully refer to the enclosed dissenting opinion of Judge Kateřina Šimáčková on the decision and the reasoning behind the Judgment of the Constitutional Court file reference Pl. ÚS 16/14 and file reference Pl. ÚS 19/14 and the attached statement of the Public Defender of Rights Anna Šabatová on these proceedings before the Constitutional Court. These opinions are the only ones at the level of the Czech Republic to deal with the issue of the adequacy of limitations imposed on the fundamental human rights in association with mandatory vaccination, concluding that the legal regulation is disproportionate and unconstitutional. We agree with these opinions and ask the Court to take these opinions and their arguments carefully into account.

On the contrary, the Czech courts avoid this factual assessment in their judgments and defend the established system of mandatory vaccination and related sanctions only by means of rhetoric and general proclamations, failing to address the Applicants' arguments and evidence at all.

#### On paragraph (i)

It is the State that its supposed to claim and substantiate the severity and impact of not carrying out vaccination according to the vaccination calendar. Due to the fact that the State does not conduct any medical analyses on these issues or ignores them, as in the case of the hepatitis B analysis not recommending the introduction of blanket vaccination, this is a failure of the State, which has failed to establish that each individual vaccination is necessary for the protection of public health.

In this case, it is worth recalling the Convention on Human Rights and Biomedicine, which the Czech Republic has ratified and which should be used as a special convention directly affecting the issue of mandatory vaccination:

The very Preamble states that the Member States are conscious that the misuse of biology and medicine may lead to acts endangering human dignity. This serves as the basis of "Article 2 – Primacy of the human being": "The interests and welfare of the human being shall prevail over the sole interest of society or science."

Article 5 contains the right to the informed consent: "An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it."

Under Article 24 – Compensation for undue damage: "The person who has suffered undue damage resulting from an intervention is entitled to fair compensation according to the conditions and procedures prescribed by law."

Under Article 26 – Restrictions on the exercise of the rights, para. 1: "No restrictions shall be placed on the exercise of the rights and protective provisions contained in this Convention other than such as are prescribed by law and are necessary in a democratic society in the interest of public safety, for the prevention of crime, for the protection of public health or for the protection of the rights and freedoms of others."

Under Article 28 – Public debate: "Parties to this Convention shall see to it that the fundamental questions raised by the developments of biology and medicine are the subject of appropriate public discussion in the light, in particular, of relevant medical, social, economic, ethical and legal implications, and that their possible application is made the subject of appropriate consultation."

For the correct interpretation of these provisions, it is necessary to consult the Explanatory Report, which states the following on individual articles:

As for the issue of the "Primacy of the human being", it states: "This article affirms the primacy of the human being over the sole interest of science or society. Priority is given to the former, which must in principle take precedence over the latter in the event of a conflict between them. ... The whole Convention, the aim of which is to protect human rights and dignity, is inspired by the principle of the primacy of the human being, and all its articles must be interpreted in this light."

As for the issue of the free and informed consent, it states: "This article deals with consent and affirms at the international level an already well-established rule, that is that no one may in principle be forced to undergo an intervention without his or her consent. Human beings must therefore be able freely to give or refuse their consent to any intervention involving their person. This rule makes clear patients' autonomy in their relationship with health care professionals and restrains the paternalist approaches which might ignore the wish of the patient. (...) The patient's consent is considered to be free and informed if it is given on the basis of objective information from the responsible health care professional as to the nature and the potential consequences of the planned intervention or of its alternatives, in the absence of any pressure from anyone."

As for the issue of "Restrictions on the exercise of rights", it states: "(...) Compulsory isolation of a patient with a serious infectious disease, where necessary, is a typical example of an exception for reason of the protection of public health. (...) The protection of the patient's health is not mentioned in this paragraph as one of the factors justifying an exception to the provisions of the Convention as a whole.

As for the issue of "Public debate", it states: "The purpose of this article is to prompt the Parties to create greater public awareness of the fundamental questions raised by the application of biology and medicine. Society's views must be ascertained as far as possible with regard to problems concerning its members as a whole. To this end, appropriate public discussion and consultation are recommended. The word "appropriate" leaves the Parties free to select the most suitable procedures. Where appropriate, for example, States may organise ethics committees and have recourse to the teaching of ethics in the field of medicine, biology and health to health care professionals, teachers and the general public."

When we apply the requirements of the Convention on Human Rights and Biomedicine to the Czech vaccination system, it is obvious that this system is contrary to the Convention:

- Based on the tragic historical experience of forced medical interventions against the will of individuals, the Convention emphasises the superiority of human beings and human dignity, which underlies the rule of free and informed consent without any pressure from anyone.
- While the Convention allows for the restriction of the right to free and informed consent, it nevertheless mentions the isolation of a patient with a serious infectious disease who is directly

endangering the environment as a typical case of restriction in the interests of public health protection. Restricting the rights of a healthy person who does not directly endanger anyone is in marked contrast to the typical case for which the Convention provides the possibility to impose limitations on the rights.

- The Convention requires the person suffering the harm caused by the intervention to be entitled to a fair compensation for that harm. Despite repeated invitations by the Constitutional Court to assume responsibility of the State for the harm caused by mandatory vaccination (Judgment file reference Pl. ÚS 19/14, or Judgment file reference. I. ÚS 1253/14), the Government ignored this task for many years. Last year, the Ministry of Health finally submitted a bill on compensation for harm caused by mandatory vaccination, but it has two major shortcomings making it inadequate in terms of satisfying the Convention's requirement for fair compensation. (1) During the legislative process, the extent of harm compensation has been substantially curtailed, which has been the subject of criticism of health care experts from both academia and practice. <sup>27</sup> The Act in a curtailed form, adopted by the Chamber of Deputies, fails to comply with the requirements of the Czech Constitutional Court, according to which the right to health also includes the principle of "full" compensation for suffered personal injury (Judgment of the Constitutional Court of 5 December 2012, file reference IV. ÚS 444/11). (2) The second shortcoming of the Act consists in the fact that it fails to compensate those who have suffered damage in the "idle" period the old Civil Code became ineffective until the effect of the Compensation Act. The Old Civil Code (No. 40/1964 Coll.) regulated the objective (including non-culpable) liability of the health service provider for harms caused by the vaccine. However, this liability has not been taken into account in the new Civil Code, therefore, since 1 January 2014, no one has been liable for the harm and the State has refused it. As mentioned above, the Ministry refused to compensate the boy who in 2015 suffered a paralysis of a half of his face as a result of mandatory vaccination, which had been confirmed by the attending physicians. Even the boy's action against the Ministry was unsuccessful, and currently the court of appeal has affirmed that the State is not liable for the harm caused, as there is no appropriate legal regulation on the matter.
- The State ha failed to comply with the Convention's requirement that the State address the fundamental issues arising with the development of biology and medicine and having significant medical, social, economic, ethical and legal implications, only after proper public debate, and that their application, if any, be subject to the relevant debate. There has been practically no public discussion. In 2015, the Ministry established the Working Committee on Vaccination with the participation of independent experts and representatives of non-profit and patient organizations. However, this group has not been convened for 3 years (since March 2017), coincidentally since the vaccinologist Roman Prymula was appointed the Deputy Minister, being in a conflict of interests. Last year, the Ministry prepared a draft amendment to the Public Health Protection Act (No. 258/2000 Coll.), which again strengthens the repression against children who are not vaccinated according to the national vaccination calendar and their families. In particular, it includes the introduction of these measures: (1) significant restrictions on the admission of pre-school children not only to kindergartens providing education and subsidized by the State, but also to any other childcare facilities, including private facilities and associations, founded by parents themselves and not receiving any subsidies from the State; (2) withdrawing the possibility for specialist doctors to issue a certificate of medical contraindication to the child; newly only the general paediatrician will be able to issue the certificate,

<sup>&</sup>lt;sup>27</sup> https://zdravotnickepravo.info/zakon-o-nahrade-ujmy-zpusobene-povinnym-ockovanim-aneb-jak-se-dobre-umysly-meni-v-nocnimury

rather than a specialist such as a neurologist or immunologist; and (3) the possibility to impose a fine of up to CZK 500,000 (nearly EUR 20,000) for the attendance of children who are not properly vaccinated. These new repressive measures have not been the subject of any public or professional debate. Moreover, the necessity to introduce further repressive measures does not follow from any analysis on the protection of public health. As indicated from the Ministry's response to the request for information submitted in January 2020 (enclosed), the Ministry did not have any such analysis carried out. The new repressive measures are merely a manifestation of the arbitrariness of the Ministry and an effort to punish at all costs children and families who do not vaccinate according to the national vaccination calendar.

In relation to the Applicant Vavřička, it should also be noted that he was fined for not having his children vaccinated, without at all finding out the views of his minor children, yet already sufficiently mature to express their views (aged 13 and 14 years). Under Article 14 of the Convention on the Rights of the Child, as well as Article 6 (2) of the Convention on Human Rights and Biomedicine, the child has the right to express themselves freely on all matters concerning them, while the child's opinion must be taken into account as a factor the binding nature of which increases gradually with the age and degree of maturity. In the case of the Applicant's children, it was necessary to establish their opinion and if they did not agree with the vaccination themselves, their opinion was supposed to be respected and they were not supposed to be compelled to undergo vaccination regardless of their will. Any such procedure would be contrary to the above Conventions and to the best interests of minors, yet the Czech authorities probably expected the Applicant to apply a coercive procedure against his children. If the Czech authorities considered that the vaccination was in the best interests of minors, they could offer the vaccination themselves to children through a GP, yet without applying repression against their father, i.e. the Applicant.

#### On paragraph (ii)

As for the scope of the exceptions to the vaccination obligation, our statement may partly be found with the Court question No. 6, where we deal with exceptions to mandatory vaccination based on the reservation of religion or conscience inferred from the case law.

The Public Health Protection Act provides for an exemption from mandatory vaccination due to "permanent contraindication". However, in practice, there have almost no cases in which a permanent contraindication would be recognised, despite the fact that many children are in a very serious medical condition. The Applicants' legal representative even found that a permanent contraindication was not even recognised for an HIV-positive child. It remains unknown how many children in the Czech Republic have a recognised permanent contraindication and how many of them attend kindergarten. The Government and its experts have repeatedly argued that children with permanent contraindications who cannot be vaccinated need to be protected by excluding unvaccinated or incompletely vaccinated children from pre-school collectives. Yet the size of this group of children who allegedly need to be protected is an unknown figure. The overwhelming majority of nursery schools in the Czech Republic are not attended by a single child with a recognised permanent contraindication. In practice, permanent contraindications are not recognised even if the child has serious health issues or if the parents have refused vaccination due to a previous negative reaction to the older child's vaccination, and these children are also denied pre-school education on the pretext of protecting public health. In addition, we refer to other applications filed against the Czech Republic: Anežka Chovancová v. the Czech Republic and Eva Vrcková and Veronika Vrcková v. the Czech Republic.

#### On paragraph (iii)

The statement on the manner in which the scope of mandatory vaccination was determined may be found above within the Court question No. 6.

#### On paragraph (iv)

Regarding the issue that the nursery school staff members are not subject to the vaccination obligation, we note that there is no vaccination obligation to the same extent as children admitted, and there is not even an obligation for nursery schools to check with their staff whether they have been vaccinated, and if so, when and against what. This inconsistency was pointed out by Constitutional Court Judge Kateřina Šimáčková and the Public Defender of Rights Anna Šabatová in their opinions to which we refer.

## On paragraph (v)

The fact that in the Czech Republic, there is no liability of the State or anyone else for the harm caused by mandatory vaccination was commented above. It should be added that the case Baytüre and Others v. Turkey (No. 3270/09) concerned voluntary (rather than mandatory) vaccination, so the conclusions of this case cannot be applied to the present case. On the contrary, we refer to the case law of the Italian Constitutional Court, which considers the situation when the legal regulation imposes on individuals vaccination as a potentially harmful interference with the personal integrity in the interests of others, while completely omitting the issue of compensation for damage to health, to be a disproportionate interference with the individual's rights and the legal regulation as unconstitutional (Decision No. 118 of 1996, Decision No. 258 of 1994, and Decision No. 307 of 1990).

#### On paragraph (vi)

The question that in the case of the Applicant Vavřička, the exemption from the vaccination obligation (a reservation based on religion and faith) was established retroactively was commented above within the Court question No. 6.

#### On paragraph (vii)

As for the question that the Applicant Novotná, at the time of the decision not to admit her to kindergarten, was already attending it, we note that Ms Novotná has been admitted to Montessori nursery school on 12 April 2006. The parents of Ms Novotná received decision to not admit her from 14 July 2008 after more than two years of attending Montessori nursery school. It is difficult to justify that a child who has attended nursery school for two years and has not jeopardised anyone suddenly jeopardised other children to such an extent that it was "necessary" to exclude her from pre-school education.

We conclude that on the basis of the above and on the basis of the arguments in the opinions of Constitutional Judge Kateřina Šimáčková and the Public Defender of Rights of Anna Šabatová, it is obvious that the State's action towards the Applicants was not adequate and necessary in a democratic society. The State's action did not consist in seeking a fair balance between the interests of the society and the requirements for the protection of individuals' rights, but in favouring a repressive and arbitrary approach, regardless of its rationality and proportionality.

Court question No. 8: If question 3 is to be answered in the affirmative, did the obligation to undergo vaccination as provided for by the domestic legislation as a condition for the admission of Mr Roleček to preschool education amount to an interference with his right to respect for his private life under Article 8 of the Convention?

Reference is made to the arguments above.

Court question No. 9 regarding Mr Roleček: If so, did this interference meet the requirements of the second paragraph of that Article?

Reference is made to the arguments above.

## 4.2. Violation of Art. 9 of the Convention

Court question No. 10: As far as the applicants Mr Vavřička, Ms Novotná and Mr Hornych are concerned, does Article 9 of the Convention apply to the facts of the present cases, having regard to:

- a) the conclusion of the domestic courts according to which Mr Vavřička failed to establish that any of his philosophical or religious views had been involved in his decision not to comply with his statutory duty to have his children vaccinated;
- b) the formulation of Ms Novotna's complaint under Article 9 before the Court with reference to the attitude and philosophical conviction of her parents;
- c) the level of cogency, seriousness, cohesion and importance of any views (see *S.A.S. v. France* [GC], no. 43835/11, § 55, ECHR 2014 (extracts)) as regards their vaccination which Ms Novotná and Mr Hornych could have held at the relevant time in view of their age;
- d) the fact that the fine imposed on Mr Vavřička and the decisions not to admit Ms Novotná and Mr Hornych to the nursery school appear to have been the result of the application of general legislation which sets inter alia an objective and neutral requirement to undergo vaccination (see *Boffa and Others v. San Marino, no. 26536/95*, Commission decision of 15 January 1998, Decisions and reports no. 92B, p. 27, and *Skugar and Others v. Russia* (dec.), no. 40010/04, 3 December 2009, with further references)?

## As for the paragraph a)

The Applicant Vavřička explained his conviction thoroughly and if the courts did not accept it there is only one possible reason why: they did not want to allow the exception from mandatory vaccination because of their ideological reasons. The Applicant's main motivation was to protect the health of his children because he was strongly convinced that vaccination causes health damage to the children. The conscience of Applicant Vavřička did not allow him to vaccinate his children for this reason or even force them into it without taking their opinion into account.

The Czech Constitutional Court admitted the possibility of religious exception from the mandatory vaccination at first. But the Supreme Administrative Court did not recognize it and the second constitutional complaint was dismissed on 24 January 2013. The conscientious objection to mandatory vaccination was recognized in latter ruling of the Czech Constitutional Court on 22 December 2015, file reference I. ÚS 1253/14. In this ruling the Court explicitly allowed (art. 45) that the conscientious objection can be based on subjective conviction about the possibility of irreversible health damage to a close person. This ruling admitted the conscientious objection of a married couple which was worried about the health damage that could be caused by vaccination

to their child. Since the Applicant's case was analogical, his conscientious objection should have been recognized as well.

#### As for the paragraph b)

The reserved attitude of her parents to the vaccination (specifically measles, rubella and mumps) was explained in the application of the Applicant Novotná. The main reason for their reserved attitude was the questionable benefit of this vaccination for the minor and the frequent unwanted reactions caused by this vaccination. Their conscience did not allow them to vaccinate the Applicant against listed diseases. They did not fully refuse other vaccinations, but they chose individually based on their conviction and best interests of the Applicant. It is important to stress that the minor has the right to parental care in conformity with parental conscience which is why she is claiming her right to freedom of conscience.

#### As for the paragraph c)

The Applicants did not have their own attitude towards vaccination at the time they were supposed to be vaccinated because of their young age. Their parents were the holders of the conviction which fulfilled requirements on cogency, seriousness, cohesion and importance. As stated in previous article, minors have the right to parental care in conformity with parental conscience and this right was violated.

#### As for the paragraph d)

The requirement of subjecting one's children to the wide range of mandatory vaccinations cannot be considered objective and neutral requirement because it is an interference with physical integrity and in some cases can cause serious health damage. Furthermore, the Government does not have sufficient medical analysis and authorities who make the decisions are often in the conflict of interests. For these reasons we cannot compare the mandatory vaccination to the assignment of the taxpayer's number (Skugar and Others v. Russia, no. 40010/04).

Court question No. 11: If so, has there been an interference and did it meet the requirements of the second paragraph of Article 9?

We refer to our arguments concerning the Court questions No. 5-7.

Court question No. 12: In particular, and in view of the fact that the impugned measures pursued general preventive public-health purposes, should the personal views of the applicants protected by Article 9 of the Convention have been allowed to prevail over the general interest of the society in the protection of public health and, if so, on what grounds?

This question assumes that all mandatory vaccinations are provided with a general public interest in protecting public health, which cannot be accepted. We have reiterated that, for instance, in the case of hepatitis B vaccination, the State commissioned an analysis of Czech experts on infectious diseases and the results did not recommend introducing blanket vaccination, as vaccination of risk groups was better and cheaper. In the case of refusing the tetanus vaccination, others are not at all exposed to any risk.

Yet even if there were a genuine general interest in every vaccination, we would like to refer to the conclusion of the Constitutional Court in the case of Mr Vavřička (Judgment of 8 February 2011, file reference III. ÚS 449/06) that "exceptional non-enforcement of vaccination cannot jeopardise the constitutionally protected interest in the protection of public health."

When dealing with the society's general interest, it is equally important to take into account the risks posed by vaccination. In the Czech Republic, only about 2-5% of all adverse effects following vaccine administration are reported and assessed,<sup>28</sup> which represent underreporting at the level of 95-98 %. At the same time, it is claimed that most adverse effects have been reported following the administration of diphtheria, tetanus and pertussis vaccines. Adverse effects are addressed by the State Institute for Drug Control, which in 2015 prepared a special issue of the newsletter on vaccines and their adverse effects.<sup>29</sup> It indicates that in 2014, nearly 800 adverse effects of the vaccines were reported, of which the vast majority (633) were serious reports. These include adverse reactions affecting the nervous system, muscular system, allergic reactions, etc. Taking into account the underreporting of adverse reactions, these are about 10,000-30,000 serious reactions per year.

#### 4.1. Violation of Art. 2 od Protocol No. 1

Court question No. 13: Have Ms Novotná, Mr Hornych, Mr Dubský and Mr Brožík and Mr Roleček been denied the right to education, guaranteed by Article 2 of Protocol No. 1? In particular, does this provision apply to the voluntary pre-school education to which they were not admitted (compare and contrast, *40 mothers v. Sweden*, no. 6853/74, Commission decision of 9 March 1977, DR 9, p. 27; *Sulak v. Turkey*, no. 24515/94, Commission decision of 17 January 1996, Decisions and Reports (DR) 84-A, p. 98; *Cyprus v. Turkey* [GC], no. 25781/94, § 278, ECHR 2001 IV; *Leyla Şahin v. Turkey* [GC], no. 44774/98, § 141, ECHR 2005 XI; and *Mürsel Eren v. Turkey*, no. 60856/00, § 41, ECHR 2006 II, with further references)?

Although Art. 2 of Protocol No. 1 does not itself determine to which levels or type of education it is to apply the Court concluded (Leyla Şahin v. Turkey, no. 44774/98) that there was nothing to suggest that the provision did not apply to all levels of education provided by the State.

The Judgment of the Constitutional Court (of 27 January 2015, file reference PI. ÚS 16/14) reaches the conclusion, that pre-school education falls within the scope of the right to education (under Art. 33 of the Charter) and that the prescribed vaccination obligation, which serves as a condition for admission to pre-school education, constitutes an interference with this right.

It is irrelevant whether pre-school education is voluntary. What is essential is that the Applicants were excluded from the possibility of using it. Article 2 of Protocol 1 ensures equal access for all to the existing educational facilities of the Member State.

For the purposes of assessing the proportionality of the interference with the right to education, it is essential that the State not only prevented the Applicants and other children in the same situation from pre-school education in "state" nursery schools, but also in private schools often set up by parents themselves.

And, as explained above, the Ministry of Health has just come up with an amendment to the law preventing unvaccinated children from access to any pre-school facility, i.e. not only to registered nursery schools, as it has been until now.

Zuzana Candigliota

on behalf of the applicants

<sup>&</sup>lt;sup>28</sup> Article: Underreporting of Adverse Effects Following Vaccine Application, 18 March 2015. Available at: <a href="http://www.tribune.cz/clanek/35530-podhlasenost-nezadoucich-ucinku-po-aplikaci-vakcin">http://www.tribune.cz/clanek/35530-podhlasenost-nezadoucich-ucinku-po-aplikaci-vakcin</a>.

<sup>&</sup>lt;sup>29</sup> http://www.sukl.cz/sukl/informacni-zpravodaj-nezadouci-ucinky-leciv-5-2015