LIGA LIDSKÝCH PRÁV

Influence of pharmaceutical companies, vaccination and advertising

Analysis of legal regulations and practice in the Czech Republic

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Contents

Introduction

Since 2005 Liga's people have been intensively dealing with the problems related to human rights in the health care system. We used our experience of legal counselling, of handling cases before courts and of training health care workers in many publications for patients[1], health care workers[2] and in analyses of various systemic problems ranging from unlawful sterilizations[3], compulsory vaccinations[4], and freedom of choice in the matter of place of giving birth[5], to compensating patients and dealing with complaints.[6]

We may say that the centre of our efforts is the support of freedom in the matters of making decisions about one's health. Considering the fact that in the countries of Central and Eastern Europe similar issues have become part of public discourse much later than in Western countries, we have recently focused on improvement of the patient-doctor relationship and on respecting the informed choice of the patient.

At the same time we are naturally aware of the fact that the individual choice is affected not only by health care workers and public bodies, but in a very significant manner also by the pharmaceutical industry, as they influence legislators, public administration, health care facilities and the consumers themselves.

By means of this analysis we would like to support public discussion on the often neglected issues of transparency and conflicts of interest related to decision-making in the matters concerning public health and problems regarding promotion of drugs and medicines. Although we have decided to deal mainly with the issues concerning vaccination, we do not try to fight against vaccination itself or to question its contribution towards eradicating many infectious diseases.

We have chosen this topic chiefly because we think that, apart from many beneficial aspects, vaccination can also have serious negative impact on children's health, and therefore it should always be the parents who decide whether their child will be given particular vaccination or not, on the basis of unbiased information. A prerequisite for an informed choice on the part of the parents is a transparent and unbiased work of public administration and a reasonable restriction on marketing activities of the pharmaceutical industry.

David Zahumenský
Chair of the League of Human Rights

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[1] The guidebooks entitled "How to be a patient in the Czech Republic and to still keep one's dignity" and "Legal help in case of involuntary hospitalizations" and all other Liga's publications concerning health care are available online at http://llp.cz/publikace/temata/zdravotnictvi/.
[2] E.g. see the guidebook called "How to reach agreement out of court" or "How to get a patient's informed consent in practice".
[3] See the policy paper entitled "Compensations to sterilized women" and the paper called "Legal countermeasures against unlawful sterilization".
[4] See the comparative analysis "Legal systems of children vaccination".
[5] See the comparative analysis "Birth assistants' care outside maternity hospitals".
[6] See the paper entitled "Patients' rights protection" and the policy paper called "Compensations for patients in cases the medical facility is not responsible for harm caused".

Excessive medical care can do harm

***An interview with Jan Hnízdil, M.D.**, in which he is talking about current problems in the health care and the responsibility for one's health, as well as discussing the influence of pharmaceutical companies and their advertising, which will be the topic of the following texts in the analysis (the interview was conducted by Jan Nouza for the "Home care" magazine in November 2010, slightly updated in January 2011)*

For the last couple of months we, the potential patients, have been literally being bombarded with news about doctors who want to go to work abroad where they would get better salary. Is the citizens' anxiety that medical care will get worse justified or not?

Working in the health care system is very demanding. If you compare the salaries that doctors get with those of judges, it needs no further explanation. It's no wonder that my colleagues are angry. The salaries the state hospital doctors have are really outrageous. Nevertheless, I don't think that we have to fear that doctors will all go abroad. Because if they did, the myth of the indispensable and almighty health care system could be torn down. It could turn out that, in the end, many people don't need health care at all. When doctors and nurses went on strike in Israel in 1970s, the mortality rate dropped to half in the "affected" areas. A similar situation was in Bogota, the capital of Columbia. During the fifty-two-day strike the mortality rate dropped by 35%. On the other hand, if a larger number of doctors leave, it will be all grist to the mill of the ministry of health as they plan to shut down small hospitals and support the big ones. This will only add to the completion of the crisis because the giant hospital complexes represent a threat to the patients' health due to their size, impersonal environment and focus on production. They are impossible to run, control and pay for. They provide ideal conditions for corruption and satisfaction of the interests of the aggressive groups of medico-pharmaceutical complex. Maybe that's why they enjoy such a great support of the State.

But how come that the medical profession is so much respected by the society and so badly paid at the same time?

Who's to blame? Who turned the doctors into poorly paid slaves? Politicians? Insurance companies? The Chamber? Oh no! We did it, we made ourselves slaves. The system based on meaningless accumulation of actions has long suited us. We have willingly reconciled to the assertion that there is no dirty money and that everything will be regulated by the hand of the market. And now we are suffering the consequences of indulgence to corruption and waste. Those few top-class doctors who were asked to work abroad have already been there for a long time. The majority of the others would probably get a higher salary, but in the foreign country they would be in the same position as Ukrainian workers are in this country. We have to solve the crisis here. There's no external cause. We have caused this situation and we will have to face the music.

During the aforementioned campaign I saw a slogan that said "Our exodus, your exitus". Isn't it a little in contradiction with ethics?

I saw the slogan. It kind of reminds me of: "If they seize you, you will perish!" It sends a chill down my spine.

Is the Czech health care system sick?

For many years the politicians have been talking about the crisis in the health care system and the need for reform. But so far no minister has succeeded in putting it in place. But the health system is merely a form in which the medical science is put into practice. The reformers proceed from the

assumption that all provided care is of good quality, purposeful and precisely indicated, and it only lacks money. Yet, this is a fundamental mistake. The medicine is in crisis as well. Great many examinations and medications are completely needlessly prescribed. A mere effort to change the form – "reform" – of the health care system is not enough. It is also necessary to change the medical way of thinking and practice.

So what is the diagnosis of the health care disease…?

The disease has three principal symptoms: fragmentation, objectification and underestimation of the doctor-patient relationship. And to all of these add up the invisible hand of the market. I'll start with fragmentation. The medicine has divided all bodily and mental functions; it has divided the human being into separate organs, tissues and groups of cells only to divide itself into specialized expert fields. Thanks to this many groundbreaking discoveries have been made, on the other hand the medical science has lost the ability to consider the detailed information in the context of individual patients' lives, the ability to develop a complex psychosomatic approach. We have learned to perfectly understand diseases but we have forgotten to understand people. For us patients have turned into "a gall bladder, an appendix, a heart attack". But in fact, they are desperate people in a difficult life situation. And we should be there to understand it and help them get through the hard times.

And objectification...

Biological medicine works on the presumption that every health disorder has its objective cause, which can be revealed thanks to examination technology and removed by means of an external intervention – medication, surgery or physical influence. However, in 2001 the British Medical Journal published the results of a study, in which the scientists examined the medical documentation of sixty thousand patients who had been examined by ambulatory specialists between 1993 and 2001. Among them they chose 361 patients whose treatment cost the health care system the most. For the first time the study featured the term "inexplicable disease". It applies to people who typically come to the doctor's office with a bodily disorder – headache, backache, heart palpitations, stomach twitching, fatigue, dizziness, nausea. They are repeatedly examined with the use of modern technology. However, in 40% of cases the doctors were unable to identify the objective cause of the patient's ailment. These problems are in fact a somatisation, or incarnation of a difficult, unsolved life situation. The patient is helpless, under stress and their body eventually starts solving the problem in its own way – by developing a disease. A biologically educated doctor sees such person as a hypochondriac, malingerer or someone who should be sent to see a psychiatrist. Only, they are really in pain. They just cannot objectively prove it.

Doctor-patient relationship?

The modern medicine goes "outside" the relationship. In the anonymous environment of big hospitals the patient doesn't know the doctor and the doctor doesn't know the patient. They know nothing about the patient's character, their idiosyncrasies, way of life, their joys and sorrows and they know nothing about the importance of these factors for establishing the right diagnosis. They have no idea that the principal role in the medical practice is occupied by the relationship of mutual trust. Uneasy and uncertain, the doctor sends the patients to various examinations and prescribes them needless medication. They do that not because it would be good for the patient's health but they do that because they don't understand why the patient is ill and they want to be insured against all possible circumstances.

And what treatment would you prescribe?

Firstly: education. So far no minister has ever talked about this. Medical faculties should provide the students with education in biological as well as in psychosocial disciplines. They should teach them to develop a complex, psychotherapeutic approach to patients, to establish a good relationship with the patient and to put their health problems into the context of the story of the patient's life. Secondly: support of general practitioners, personal and family physicians. They represent the key factor that determines the quality of the whole medical practice. A general practitioner is closest to the patient's life, they know their character, family relations, their profession, their joys and sorrows... They can reveal the actual cause of the patient's ailment without the necessity of expensive examinations, and they can cure the patient quickly and effectively. Thirdly: stop subsidizing big hospitals and start establishing small facilities that would offer such conditions that are closest to the natural family surroundings of the patient – with quality food, friendly treatment and no unnecessary waking-up in the morning. However, such changes would mean a catastrophe to the medico-pharmaceutical complex as their income depends on the number of people who are receiving treatment and not on the number of people who recover. Therefore I fear that the current health care system is impossible to reform. Most likely it will totally fall apart. And neither the Ministry nor the politicians would save us. Unless we want to wait till the bitter end, we should stop threatening the patients with our departure abroad and we should join our forces and start working on creation of a new system of health care and medical practice.

I have here your book entitled "To my sick people or How to make a patient". Doesn't the title of this collection of short essays about some doctors' practice sound quite malicious towards your colleagues, doctors?

Surely, this wasn't the purpose. I could write dozens of books about great physicians, miraculous remedies and unbelievable achievements of modern medicine. Using the stories of patients, I wanted to point at the limitations and dangers that arise from a narrow biological view of a sick person and from a commercial-industrial approach to medicine.

In the very same doctors' offices we can hear that doctors must now do more paperwork, which takes up the time they could give to treating patients – and then later, they have to go on visits to patients...

This really is the case. A much greater emphasis is put on carefully doing the "paperwork", rather than on trying to see whether the medical visit did the patient any good or not. Not long ago I have read a study on procedures of examination of patients complaining of backache, which had been carried out in Sweden. Nearly every patient was automatically sent for a spine X-ray. So as not to neglect anything. However, it turned out that the X-ray can do very little to help establish the diagnosis without a previous knowledge of the patient's way of life. An unexpected finding that would be significant for the treatment was revealed only in one out of 2,500 patients' X-rays. The rest of the patients were, lege artis, sent for an X-ray quite unnecessarily. If the doctor tried to get to know the patient better, they would quickly understand what message the backache brings. And at once, there would be less medication as well as less paperwork. We have accepted to play this game, and so we will pay for it.

In waiting rooms and elsewhere as well, we can hear a voice saying that doctors send the patients to their colleagues to get various – and often needless - examinations, and that the reason of it is to maintain a chain of interventions and points!

But it's not only the doctors' fault. It's the basis of the whole system. I pass it on my colleague, they pass it on me. Whoever breaks the chain, stops conducting examinations, prescribing medication, is out of the system. I have experienced it myself. After graduating I started working at the convalescence centre of the General University Hospital in Prague. I found the routine mechanical medi-

cine unsatisfactory. Every day patients kept coming to see me about their various pains. I used to send them for various examinations, prescribe various medications. The patients accepted the treatment but they didn't get better. I didn't understand why they were sick. And then I met a colleague, Mr Šavlík, the founder of psychosomatic medicine in the Czech Republic. When I asked him, what his medical discipline is, he told me: "While other doctors treat patients for diseases, I tell people what they can do in order to get better." I liked that. I realized that every disease represents a piece of information about some mistake the patient makes in their life. I started getting to know my patients better, I started asking about their way of life, their joys and sorrows. It has opened up a new horizon. I started to understand the ailments of my patients and was able to give them advice. Those who understood started to recover. And that was the end of me. I broke the chain of interventions and points and my workplace was cancelled for reasons of "economy".

Does this have anything to do with one of your other statements: "The fact that patients are not happy unless they leave the doctor's office with a prescription in their hand is not their fault? We, doctors, have brought them up like this"?

Doctors treat the patients in a mechanistic manner, and patients treat themselves in a mechanistic manner as well. This is what we have been taught at the medical faculties, and that's what we have taught our patients. When I worked at an outpatient clinic of the university hospital, I often felt like a car mechanic. The patient would come there with their faulty body and would list the defects: "My back is blocked – please, unblock it. My knee is squeaky – please, apply an injection of grease. Check pressures and level of fat..." Then, they would lay aside their body and wait for the medical mechanics to repair it. But God help them if the repair went wrong. "It must have been a bad doctor, they didn't send me for X-ray, they didn't prescribe me any expensive medication. I must go to a better garage, a better hospital," the patients would say. Those people don't understand at all the value of information the disease gives them as well as they don't understand that they are also to blame. The way you live is the way you get sick, and unless you change your way of life, you cannot get better.

You said that advertising of drugs is the historically biggest chemical experiment on humans. Isn't this scaremongering?

Yes, you got it right. I really am sounding the alarm. A deterrent example is the cholesterol. You surely have heard that: "After cancer, cholesterol is the biggest enemy of humanity." And I'm sure you know that: "A higher level of cholesterol represents one the most significant risk factors in the development of atherosclerosis and its complications: for example, heart attack, cerebrovascular accident or lower limb ischemia.". So there's no time to lose, let's hurry up to see a doctor. And God help you if there's more than 5.5mmol/l in your blood. Then you're sick. You have a disease – hypercholesterolemia. It doesn't matter that up to now you were feeling good. In a historically short time the medical propaganda succeeded in spreading a mass panic. People have become obsessed with measuring its level. Fibrates and statins have become the top-selling drugs in history. In 2006 the world producer earned 27.8 billion dollars. And they're doing great in this country as well. They are being taken by nearly a million of Czechs and they represent the most administered drugs. Nevertheless, we slowly start sobering up. "Lowering the level of cholesterol can do no good to healthy people. Neither is there a great benefit to patients who have already suffered from a heart attack. Regular exercise can do them much more good than drugs.", says Professor Rodney A. Hayward of Michigan. And he's not the only one. But the sickness dealers would not like that one bit. It seems that we have risen to their greasy cholesterol "bait". More than from the cholesterol itself people nowadays suffer from the drugs against it.

I know that your field of study and interest is the psychosomatic convalescence and pain management. Can you, please, explain it in layperson's terms?

Psychosomatic medicine is also called medicine of stories. If a patient comes to see me, I first have to get to know the story of his illness – when and how it has started, what kind of examinations he underwent, what treatment he got and what the results of it were, and I examine him closely – I put together his medical history. But at the same time I want to know whether he went through any hard times in his life – I put together his personal history. Then I compare the two histories, and I find out that he has suffered from headaches and high blood pressure ever since his divorce court trials... he had a heart attack when he lost his important manager position... he started suffering from heartburn when his son started taking drugs. The illness has become an embodiment of his life situation. This is best illustrated by popular idioms: "he is in over his head... it broke her heart... it made their stomach turn".

And can you do without any chemistry using this kind of therapy?

Patients are able to deal with most of their health problems themselves. They just need to know how to do that. And I think that's where the doctor comes in – they should guide the patients through the hard times in their life. I use medication as well as modern technology but I use it with economy. The most important thing is to understand what information the illness brings, what mistake the patient makes in their life and how they can change their behaviour in order to get better. The most effective medication is the self-healing power. This has to be encouraged. Nevertheless, if the patient's own power is not enough to help them recover from the illness, I prescribe them some medication. But I keep in mind that drugs are not a long-term solution. They can help them find enough strength to bring about the necessary change.

All media are full of all kinds of fights – even against ageing. If my father, who was a farmer, still lived, he would probably say: This is against nature! Are you of the same opinion?

Ever since we're little children we are taught, trained and prepared for our future work, our professional success but no one, not our family, not the school, prepares us for the fact that we will grow old, we will die. For many people the normal ageing process represents a considerable stress. The society requires them to give a continuous performance, they occupy managing positions, they don't know how to relax, and then, suddenly, their bodies start indicating that something is wrong. They don't understand that they are less and less strong and they expect that medicine will help them. The pharmaceutical industry have sensed that and they immediately started making advantage of the demand for eternal youth. A new medical discipline has been introduced, the anti-aging medicine. The purpose isn't to help people come to terms with a completely natural process; the purpose is to force them to take drugs, to turn ageing into a disease. In medicine we call it publicizing – taking an everyday life problem and turning it into a disease. My grandmother would say: "Human stupidity is endless, there is no drug against old age".

How do you feel about the incessant repetition of the number of working-age people who have to support sick and old people, and about the fact that the ministers of social affairs, and health respectively, do not strongly oppose that?

This presents one of the greatest paradoxes of the modern medicine and society as a whole. On one hand, we can keep old people alive thanks to modern technology and medication in situations that are incompatible with life. On the other hand, the number of old people dependent on medication and technology quickly increases. Their life span may be prolonged but the quality of their life doesn't correspond. They are spending the rest of their lives in desperate situations, alone or in retirement and nursing homes. There are many old people and the society isn't prepared for this. Surely, that doesn't mean that old people shouldn't get good medical care. However, what is also important is the psychical, social, community and hospice support. This topic is too serious and

little attractive to the media. Politicians try to avoid it at all costs. They can win more popularity in the "heroic" battle over regulatory fees.

Not by the way – in September 2010 you sent an open letter to Mr Heger, the Minister of Health, suggesting some anti-corruption measures the Ministry can take. Did he reply? And if so, what did he say?

It's the regulatory fees all over again. Just note for how long the politicians have been arguing about them. It is a ridiculous sum of 30 CZK, though. A couple of hundreds of millions in total. According to the reasonable estimate of the Czech chapter of Transparency International the corruption in the health care system costs this country about twenty billion CZK a year. Yet, the politicians keep modestly silent about it. I have pointed out the problems of corruption to several ministers, I have sent many propositions. Two years ago I got a vague reply from the legal department of the Ministry of Health. I counted twelve grammatical errors in the letter. I tried it again this autumn. So far minister Heger hasn't replied. I have no delusions about it. The medico-pharmaceutical complex is so riddled with corruption, that the latter cannot be eradicated without destroying the whole medico-pharmaceutical complex. I think that minister Heger is beginning to understand this as well. Not long ago he said that he thought he would not stay minister for long.

It is mainly the elderly people who may feel "cornered" by the natural deterioration of their bodies and who therefore seek help anywhere they could – very often from healers as well. What do you think about the so-called alternative medicine?

Years ago I was a member of Sisyfos, the Czech Sceptics' Club. I protested against acupuncture, homeopathy, biotronics. Nevertheless, I started to wonder how it was possible that the alternative methods could help so many people although they weren't supposed to. And psychosomatics provided me the explanation. Doctors' offices are visited by many anxious, neurotic or depressed patients. Their physical problems have a very strong psycho-social context. These patients mostly expect the doctor to be helpful and understanding, to give them comprehensible explanation and to calm them down. Instead of this, they are exposed to a never ending succession of examinations and medical interventions that neither help reveal the cause of the patient's problems and nor remove it, but that rather increase the patient's anxiety and unease. No wonder that these patients turn to healers. Healers may lack profound theoretical knowledge and modern technologies but they can get better results merely by meeting the patient in person, establishing a relationship of trust, getting to know the story of the patient's life, and finally by applying the magical healing methods. And if, moreover, the healer is an emphatic person with rich life experiences and intuition, they are able to calm down the patients, to advise them about their problems, to adjust their diet, to motivate the patient to change their behaviour. Unless the medical science admits its failure and realizes that the best medication is the personality of such therapist who is able to consider things in context, it will only helplessly watch the healers trespass its "holy" ground.

Isn't now the time to go back? Would you know which way to take...?

Do you want to know the way to health? What is health? I think that it is the ability to handle problems of everyday life. If you are strong and willing enough to solve the problems, you are healthy. If you start losing the will to go on, you are uneasy. And if you become unable to handle the problems, you are ill. But what do you need to be contented and healthy? Apart from nourishment, exercise and physical condition you need love, friends, culture, good relationships and healthy environment. There is not much space left for them in competitive market conditions. In the past, it were merely the philosophers who pointed that out, nowadays they are joined by economists as well. Luisa Corrado, of the Faculty of Economics of the University of Cambridge, studied the relation between the economic growth and the contentment of the citizens. Twenty thousand people

from 180 areas of Europe have recorded the extent of their happiness in a questionnaire. It was expected that the best results would be achieved by people living in the prospering countries of the sunny south of Europe. Surprisingly, the best results were achieved by the Danes, followed by the Finns, Irish people and Swedes. It turned out that more important than the growth of GDP is the trust in the state administration, law enforcement and good interpersonal relationships. And that's exactly what's missing in this country. Healthy people cannot live in a sick society. That's why I try to warn people. Against being manipulated by the politicians, advertising, medico-pharmaceutical complex. Encourage them to take over the responsibility for their own life and health. The most effective medication is the establishment of civil society. And that's up to each one of us. No politician can do this for us.

Vaccination of Czech children governed by pharmaceutical lobby

Zuzana Candigliota

Regular vaccination of children obviously exists in all Western countries, but unlike in the Czech Republic, in Western countries the basic vaccination is mostly voluntary, recommended and paid for by the State and it is also the State that is responsible for possible adverse effects.[7] In our country, the system is set up in such way as to nicely suit the vaccine producers – mainly the GlaxoSmithKline Company (hereinafter "GSK"), which is an almost exclusive supplier of children vaccines to the State[8]:

- Decisions about the extent of vaccination are made after a public and expert discussion, but it is made by a few individuals at the Ministry of Health. This makes the decision-making process non transparent and creates room for corruption.
- The decision-making process includes in a significant way people with connections to producers of vaccines or people may not act in the best interests of children. Those people are in positions in which they can issue recommendations that are in the interest of certain vaccine producers but not so in the interest of the vaccinated children.
- Neither the State nor the pharmaceutical companies have any responsibility for possible adverse effects of the vaccines. For now the possible legal responsibility falls on the doctors administering the vaccines,[9] who, therefore, have no motivation to report any side effects; only a fractional number of side effects are ever reported. This means that there are no objective data on the vaccines safety. There are no known cases of compensation awarded for adverse effects of vaccination.
- Vaccination is "compulsory" to a great extent, meaning that if the parents of the child refuse or postpone the vaccination, they can be reported to the authorities and get fined. No law provides for interrogation of older children about their opinion. This significantly disrupts the relationship of trust and partnership between the doctor and the family, as well as the doctor's obligation to provide unbiased information about the vaccination.

The current system of children vaccination does not respect many of the requirements defined in the **Convention on the Rights of the Child**, which requires that in all actions concerning children, the best interests of the child should be a primary consideration and that such protection and care

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[7] Legal systems of children vaccination – the analysis of legal regulations in selected European countries. The League of Human Rights, 2010. Available at (only in Czech): http://llp.cz/wp-content/uploads/Pravni_systemy_ockovani_deti1.pdf.

[8] Upon the request for information submitted in 2009 and concerning *"vaccines (commercial names) that are covered by the State"*, the Ministry of Health, represented by the public health officer Michael Vít, replied: *"The State covers vaccines InfanrixHexa, Infanrix, InfanrixHib, Boosterix/IPV, Imovax, Engerix B (for adults and children as well), Priorix, Prevenar, Pneumo 23, Alteana, vaccines against influenza administered according to the immunization schedule, as defined in the regulation No. 537/2006 Coll., and regulation No. 65/2009 Coll., on vaccination against infectious diseases, and Avaxim in case of an exceptional vaccination against hepatitis A."*

[9] The doctors are objectively responsible for any damage caused by the vaccine administration according to § 421a of the Civil Code and they cannot evade the responsibility, although it is the State that orders them to administer the vaccines. For more information see e.g. the text by Radek Policar entitled "Responsibility for adverse effects of compulsory vaccination", published on 16th February 2012, in Zdravotnické noviny. Available at (only in Czech): http://www.zdn.cz/denni-zpravy/profesni-aktuality/odpovednost-za-nezadouci-ucinky-povinneho-ockovani-463478. Nevertheless, the new Civil Code that will come into effect on 1st January 2014 cancels this responsibility but so far the State has not assumed this responsibility.

should be ensured as is necessary for his or her well-being and that due weight should be given to the views of the child in accordance with the age and maturity of the child.

Neither are respected some provisions of the **Convention on Human Rights and Biomedicine**. For one thing, the patient's right to fair compensation for damage due to vaccination is not ensured, as such right is purely theoretical and difficult to put into practice. Secondly, as far as vaccination is concerned it is not the subject of appropriate public discussion in the light of relevant medical, social, economic, ethical and legal implications, as is required by the Convention. Another right that is not respected is the right to give an informed consent as well as the only exception, which says that this right can only be restricted in cases in which it is necessary in a democratic society for the protection of public health.

The following text will mainly deal with the non transparent manner in which decisions about vaccination are and were made in the Czech Republic, and with the manner in which key positions are allocated to people with significant connections to the vaccine producers. It will also point at suspicious decisions made by authorities under the influence of these people that seem to be more in the interest of the vaccine producers than in the interest of the vaccinated children.

Non transparent decision-making about vaccination

Inadequate legal regulations concerning vaccination

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.

Presently, **the practice of courts is not clear on the point whether the current legal regulations concerning vaccination are in contradiction with the constitution or not**. One of the Senates 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. However, it is necessary to mention that other Senates have a different legal opinion on the given/same question and do not see any contradiction with the constitution. The Constitutional Court has not given their opinion yet, although they had an opportunity to do so.[10]

[10] Finding of the Constitutional Court delivered on 3rd February 2011, File No. III. ÚS 449/2006.

Nevertheless, there are more reasons in favour of the anti-constitutionality of the current legal regulations. For one thing, the Constitutional Court already commented on essentially the same matter and they observed that it is unacceptable to have the extent of fundamental rights and basic freedoms defined by other than lawful regulations. Otherwise the field of protection of fundamental rights and basic freedoms would go under the executive branch, which, however, is not authorized to decide about these matters.[11] In another of their decisions the Constitutional Court explained that the restriction on matters defined by lawful regulations is there to protect individuals against executive branch excesses.[12] It is also relevant to draw a comparison with the rare countries of Western Europe, in which some vaccinations are compulsory (France and Italy), and in which the extent of this obligation, that means the particular diseases, against which individuals have to be vaccinated, is defined by the law.[13]

The current legal regulations are controversial from the point of view of constitutionality, and they are also in contradiction with a transparent debate and public discussion, which would otherwise be held in the Parliament. And what's more, it even helps create an environment of corruption, in which it is enough to influence a few people who exercise the power to decide. On the other hand, it is true that not even the Parliament can vouch for an unbiased discussion without trying to push through individual interests. That is why it would be ideal to have the lawfulness of a regular vaccination reviewed by a special expert body, which would be independent and trustworthy.

Decision-making and other activities of the Chief Public Health Officer before the establishment of the National Advisory Committee on Immunization

As we have previously explained, it is the Ministry of Health who decide about vaccinations that will be made compulsory by issuing a relevant regulation. However, it is not clear what mechanism and criteria were used to support the decisions made both in the past and in present. The only thing that is certain is the fact that from 2000 to this day, the person who made the decisions has been Michael Vít, the Chief Public Health Officer and the Deputy Minister of Health.

Michael Vít's career was significantly cut short only in March 2012, when he was forced to obtain an unpaid leave of absence due to criminal prosecution. He has been replaced as the Chief Public Health Officer by an appointed deputy. However, the name of his successor is already being discussed as the police have accused Michael Vít of abuse of authority and breach of duty concerning other people's property management. They also charge him with manipulation of public contracts.[14]

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[11] Finding of the Constitutional Court delivered on 10th July 1996, File No. Pl. ÚS 35/1995.
[12] Finding of the Constitutional Court delivered on 14th February 2001, File No. Pl. ÚS 45/2000.
[13] In particular, in France it is compulsory to be vaccinated against three diseases, as it is defined in the Act on Public Health (Code de la santé publique). Art. L3111-2 and art. L3111-3 of the Act define the particular diseases against which a person has to be vaccinated. Another country, in which vaccination is compulsory, is Italy. The obligations concerning every vaccination, including the period of time in which they have to be done, as well as other conditions, are stipulated by particular acts (Act No. 51/1966 G. U., on obligation of vaccination against paralysis, Act No. 891/1939 G. U., on obligation of vaccination against diphtheria, Act No. 292/1963 G. U., on obligation of vaccination against tetanus, Act No. 165/1991 G. U., on obligation of vaccination against hepatitis B).
[14] Biography of and basic information about Michael Vít available at (only in Czech): http://cs.wikipedia.org/wiki/Michael_V%C3%ADt; Article entitled "Heger: Obviněný Michael Vít buď odejde z funkcí sám, nebo bude odvolán" ("Heger says: Either Michael Vít resigns or he will be dismissed"), published on 14th March 2012, Czech Radio, available at (only in Czech):

Nevertheless, neither have the previous activities of Michael Vít been free of problems. In many cases it is suspected that his primary concern has not been the protection of public health. For example, in 2010 he ranked second in a yearly public inquiry relating to the worst anti-ecological act for suggesting and enforcing the increase of traffic noise levels, in spite of the fact that more than one million people were affected by overly high and health-endangering noise levels. Furthermore, he adopted a passive attitude out of a preliminary carefulness and did not forbid the manufacture and use of baby bottles containing the dangerous Bisphenol A, although many Western countries have done so.[15]

As far as Michael Vít's activities in the field of vaccination are concerned, it is questionable whether he has always acted in the interests of children during the long years he worked as the Chief Public Health Officer. As we will further demonstrate, he has introduced new vaccinations in the immunization schedule in a non transparent manner and without any proper expert explanation. For many years he has ignored experts calling for the cancellation of the dangerous global vaccination of newborn babies against tuberculosis, thus indirectly causing the death or health problems of many children. Furthermore, he has refused to hold any objective discussion on serious adverse effects of vaccination and he has neglected the necessity to implement the responsibility of the State for any adverse effects of compulsory vaccination of children.

It is necessary to emphasize the practical consequences of such system, in which there are no lawfully defined restrictions on the introduction of new kinds of vaccines and in which, at the same time, there are no defined criteria, and in which the decisions are taken by a single person, whose character is publicly exposed only years later.

Introducing new compulsory vaccinations without giving the reason why

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

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http://www.rozhlas.cz/zpravy/spolecnost/_zprava/heger-obvineny-michael-vit-bud-odejde-z-funkci-sam-nebo-bude-odvolan--1031928.
Article entitled "Obviněný hlavní hygienik Vít si chce vzít neplacené volno"("Chief Public Health Officer Vít to obtain unpaid leave of absence"), published on 14th March 2012, Czech Radio, available at (only in Czech): http://www.rozhlas.cz/zpravy/spolecnost/_zprava/obvineny-hlavni-hygienik-vit-si-chce-vzit-neplacene-volno--1032118.
Article entitled "Už se hledá nový hlavní hygienik"("On the lookout for a new Chief Public Health Officer"), published on 15th March 2012 in Lidové noviny, available at (only in Czech): http://www.tribune.cz/clanek/26056-uz-se-hleda-novy-hlavni-hygienik.
Chief Public Health Officer asks for unpaid leave of absence, 14th March 2012. Available at (only in Czech): http://www.ceskenoviny.cz/zpravy/hlavni-hygienik-vit-pozadal-o-dlouhodobe-neplacene-volno/768754&id_seznam=22681.

[15] http://www.ropak.detizeme.cz/ropak/54-ropak-2010.html#kandidati.

material for decision on further strategy for vaccination against Hepatitis B to the Chief Public Health Officer, a predecessor of Michael Vít.[16]

Although there has been no known subsequent study that would obtain different results, and although the epidemiological situation has not changed either,[17] 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.

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.[18]

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.[19]

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

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[16] 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.
[17] Institute of Health Information and Statistics of the Czech Republic.
[18] Article entitled „Zubová interpeluje Juráskovou kvůli TBC očkování" ("Zubová interpellates Jurásková on vaccination against TB"), published on 13th May 2010, available at (only in Czech): http://www.moravskoslezskenovinky.cz/zpravy.php?id=8a4b98dc-afe1-102d-9f31-003048330e04&style=print;
Article by Vojtěch Thon entitled „Imunologické principy bezpečného očkování dětí" ("Immunological principles of safe vaccination of children"), in Pediatrie pro praxi, 11(6)/2010. Available at (only in Czech): http://www.pediatriepropraxi.cz/pdfs/ped/2010/06/01.pdf;
Article by Vojtěch Thon entitled „Bezpečné očkování nejen proti tuberkulóze" ("Safe vaccination against tuberculosis"), published on 29th April 2010, in Zdravotnické noviny, available at (only in Czech): http://www.zdn.cz/denni-zpravy/komentare/bezpecne-ockovani-nejen-proti-tuberkuloze-451356.
[19] Ibid.

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.[20] Nevertheless, 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.[21]

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.[22]

Refusing objective discussion and provision of information on serious matters concerning vaccines

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.[23]

The Ministry had also proved its inability to objectively react to any notification of possible dangerous effects of vaccines given by experts, as the Ministry immediately and vigorously refused such suspicions. In a morning show aired on TV Nova on 26th May 2009 immunologist Jan Šula presented information about a possible relation between the increasing number of autistic children and the use of hexa vaccines, which he had supported by his practical experience and an undefined foreign study. Instead of properly verifying this statement and looking up more information about the mentioned study, the Ministry responded by issuing a press release on the following day, saying that the guest's utterances were untrue and that the Ministry dissociate themselves from these, together with some expert medical associations, which will be further mentioned, as they have a

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[20] Article by representatives of professional associations entitled „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): http://www.ockovanideti.cz/aktuality/BCG_vakcinace_09.htm;
Article by representatives of several professional associations entitled „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):
http://www.solen.sk/index.php?page=pdf_view&pdf_id=3911&magazine_id=4;
statement by Vojtěch Thon entitled „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):
http://www.tribune.cz/clanek/17373-nove-ockovani-proti-tbc-pomaha-vsem-detem;
statement by Roman Prymula and Roman Chlíbek entitled „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): http://www.tribune.cz/clanek/17375-ad-nove-ockovani-proti-tbc-pomaha-vsem-detem;

[21] 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.

[22] See previous footnotes.

[23] 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): http://www.otevrete.cz/hodnoceni-uradu/soutez-otevreno-zavreno/archiv-souteze/2010/nominace-zavreno-pristup-k-informacim-2010-280.html#16.

provable connection with the producer of the hexa vaccine, the GlaxoSmithKline Company.[24] Yet the Ministry had not presented any objective arguments or references to scientific findings that would prove that the physician's words were untrue. At the same time even a layperson can find out that the number of autistic children is globally increasing in spite of better diagnosing, and that the causes of this state are uncertain.[25]

It is therefore clear that the Ministry had refused to hold an open and objective discussion on such sensitive topics as are serious adverse effects of vaccines. In the previously mentioned cases the Ministry chose to give no or only partial answer to any questions and to question and refuse to deal with any serious suspicions concerning a particular vaccine without giving any reason why, and the Ministry did all of this in cooperation with associations connected to the producers of the given vaccines, which will be proved further on.

Establishment of the National Advisory Committee on Immunization (NIKO)

Since 2010, when the so-called National Advisory Committee on Immunization – NIKO (hereinafter the "Committee") was established at the Ministry of Health, following an order given by the Minister of Health, the decision-making process concerning the immunization policy have become more transparent to a certain extent.

The main task of the Committee is to devise the best strategy on immunization policy in the Czech Republic for prevention of such infectious diseases that can be prevented. Among its other goals we can mention the identification of infectious diseases, the spread of which can be affected by a regular, special or exceptional vaccination, the determination of priorities in the field of vaccination and discussion on changes to immunization strategies, following suggestions put forward by the professional associations of the Czech Medical Association of J. E. Purkyně (hereinafter the "CzMA"). It is an advisory body of the Minister of Health, and its activities are accounted for by the Chair, the Chair being the Chief Public Health Officer.[26]

The Committee consists of representatives of the Ministry, Czech Vaccination Society, member of CzMA, Czech Pediatric Society, member of CzMA, Professional Society of Primary Care Paediatri-

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[24] The press release of the Ministry of Health entitled „Reakce Ministerstva zdravotnictví ČR na informaci vysílanou ráno 26. 5. 2009 televizí Nova" ("Reaction of the Ministry of Health to the information aired in the morning of 26th May 2009 on TV Nova"), issued on 27th May 2009. Available at (only in Czech): http://www.mzcr.cz/dokumenty/reakce-ministerstva-zdravotnictvi-cr-na-informaci-vysilanou-rano-televizi-nova_1343_868_1.html.

[25] E.g.: article entitled „Autismus: rostoucí problém populace" ("Autism: a growing problem of population"), published on 17th February 2012, in Zpravodajský portál Masarykovy univerzity online muni.cz. Available at (only in Czech): http://www.online.muni.cz/komentare/2747-autismus-rostouci-problem-populace.
Article entitled „V USA trpí autismem zhruba milion dětí" ("Approximately million of American children suffer from autism"), published on 30th March 2012, in ČTK (Czech News Agency). Available at (only in Czech): http://www.iporadna.cz/duse/clanek.php?article%5Barticleid%5D=25203.

[26] Website of the Ministry of Health – Purpose and aim of the National Advisory Committee on Immunization (only in Czech):
http://mzcr.cz/Verejne/Soubor.ashx?souborID=10173&typ=application/pdf&nazev=C%C3%ADle%20a%20zam%C4%9B%C5%99en%C3%AD.pdf;
The statute of the National Advisory Committee on Immunization (only in Czech):
http://mzcr.cz/Verejne/Soubor.ashx?souborID=10961&typ=application/pdf&nazev=Statut%20N%C3%A1rodn%C3%AD%20imuniza%C4%8Dn%C3%AD%20komise%20web.pdf.

cians, member of CzMA, Infectious Diseases Society, member of CzMA, Society for Epidemiology and Microbiology, member of CzMA and the National Institute of Public Health.[27]

Currently, the Committee has 13 members with medical education who are listed below:

Post in the Committee	Person[28]	Post for nomination[29]
Chair	Michael Vít	Chief Public Health Officer (most likely suspended)
Vice-Chair	Hana Cabrnochová	Professional Society of Primary Care Paediatricians, member of CzMA
Secretary	Jozef Dlhý	Ministry of Health (department of Public Health Protection, Epidemiology section)
Member	Vítězslav Vavroušek	Ministry of Health (Deputy Minister of Health Care)
Member	Roman Prymula	Czech Vaccination Society, member of CzMA
Member	Vilma Marešová	Infectious Diseases Society, member of CzMA
Member	Roman Chlíbek	Czech Vaccination Society, member of CzMA
Member	Jitka Částková	The National Institute of Public Health, Prague
Member	Josef Trmal	Society for Epidemiology and Microbiology, member of CzMA
Member	Zuzana Vančíková	not possible to find out, which professional society she represents
Member	Stanislav Konštacký	Society of General Practice, member of CzMA
Member	Vladimír Dvořák	Czech Gynecological and Obstetrical Society, member of CzMA
Member	Václav Šmatlák	Czech Association of General Practitioners

The Chair, Vice-Chair, Secretary and members of the Committee are appointed and dismissed by the Minister of Health. The membership is honorary. The membership is terminated by dismissal either from office or from employment, resignation letter or death.[30]

Strongly "pro-vaccination" composition of the Committee

The members of the Committee were appointed in a one-sided manner, they are representatives of the so-called "pro-vaccination" groups. For a more balanced composition, the Committee should also accept experts, who are able to consider the dangers the vaccination may pose, as well as the physical strain, and who are therefore capable of criticizing some uncritical supporters of vaccination in the Committee. For example, there are no representatives of the Czech Neurological Society, member of CzMA, the Society of Paediatric Neurology, member of CzMA, the Czech Society of Allergology and Clinical Immunology, member of CzMA. And yet it is vital that the Committee's composition should be well-balanced in order to be able to properly consider the strain of certain schemes and variants of vaccination on children.

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[27] Art. 3 of the Statute of the National Advisory Committee on Immunization.
[28] Website of the Ministry of Health – Composition of the National Advisory Committee on Immunization (only in Czech): http://mzcr.cz/Verejne/Soubor.ashx?souborID=12969&typ=application/pdf&nazev=Slo%C5%BEen%C3%AD%20N%C3%A1rodn%C3%AD%20imuniza%C4%8Dn%C3%AD%20komise%20web_09_2011.pdf.
[29] The documents available on the website of the Ministry of Health did not mention which institution or professional association every member represents, therefore it was necessary to look up the information on the individual websites of every professional association and on the Internet.
[30] Art. 3 of the Statute of the National Advisory Committee on Immunization.

The only expert in allergology is Zuzana Vančíková, who is at the same time paediatrician and pulmonologist, but who is also very supportive of vaccination. For example, she repeatedly promotes the vaccine Prevenar produced by Pfizer[31] and she gave lectures in favour of vaccination by this particular vaccine at a company symposium organized by the vaccine producer within the framework of the Congress of Paediatrics and Paediatric Nursing.[32] In her lectures she emphasizes solely the benefits of the vaccination and does not mention its possible risks.

Another group of people who are not involved in the Committee, and should be, are independent and respected experts on vaccination and vaccines production, such as Marek Petráš, operator of the website www.vakciny.net, which provides information about current professional trends in the field of vaccination and an online Q&A. Although Marek Petráš does not in any way oppose vaccination, he positively adopted a critical attitude towards the vaccination policy in the Czech Republic, and he also pointed at the influence of "pharmaceutical experts" upon the decisions concerning immunization schedule, which is why the Chief Public Health Officer Michael Vít took a strong dislike to him.[33]

According to the Committee Statute it is possible to invite also external experts to the Committee meetings, who are not members of the Committee, however, they only have an advisory vote.

It remains to be answered whether the Committee meetings should not be also attended by laypersons, especially parents and representatives of civic associations focusing on vaccination and promoting parents' informedness about the matter. It would also be worth considering whether some of the Committee members should not be representatives of an independent and trustworthy body, such as the Office of the Public Defender of Rights or the Government Commissioner for Human Rights. Such attendance could be beneficial for many reasons – it could help make the Committee activities more transparent, put more emphasis on provision of easy-to-understand information and on the child's interest from the point of view of parents or independent bodies, etc. Such element is completely missing in the Committee.

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[31] E.g.: her article on the benefits of Prevenar entitled „Širší ochrana kojenců a dětí před pneumokokovými onemocněními novou 13valentní konjugovanou vakcínou – Prevenar 13" ("A broader protection of infants and children against pneumococcal diseases with the use of the new 13-valent conjugate vaccine – Prevenar 13"), published in Vakcinologie No. 3/2010, article summary available at (only in Czech): http://www.medakta.cz/cislo.php?casopis=vakcinologie&rocnik=2010&cislo=3#350;
article entitled „Komplikované komunitní pneumonie u dětí" ("Complicated community-acquired pneumonia in children"), published in Pediatrie pro praxi No. 10/2009, available at (only in Czech): http://www.pediatriepropraxi.cz/pdfs/ped/2009/02/14.pdf;
lecture on Prevenar 13 given within the framework of the Conference on Paediatric Pulmonology held in 2010, information available at (only in Czech): http://www.tribune.cz/clanek/18069-co-hybe-detskou-pneumologii-v-roce.

[32] Lecture entitled „Účinná prevence pneumokokových onemocnění" ("Effective prevention of pneumococcal diseases"), abstract of the lecture available at (only in Czech): http://www.solen.cz/incpdfs/act-000059-0001_10_2.pdf.

[33] In 2006 the Chief Public Health Officer Michael Vít vigorously protested against an article by Marek Petráš, which he wrote in reaction to the introduction of hexavalent vaccine in the immunization schedule for children. Vít did not like the mention of the fact that "company experts" participate in the decision-making process, however Marek Petráš insisted on this designation, saying that "pharmaceutical companies (through their associations, etc.) always make comments on any draft acts and regulations" and he published his communication with Vít. Source (only in Czech): http://www.vakciny.net/AKTUALITY/akt_2007_01.htm.

Unresolved conflicts of interest in the Committee

A conflict of interest is a situation, which occurs when an individual or organization is involved in multiple interests, one of which could possibly corrupt the motivation for an act in the other.[34] As far as the Committee activities are concerned, this problem is not satisfactorily resolved.

Although, the mention of conflict of interest was added to the Statute of National Advisory Committee on Immunization on 31st March 2011, in particular it says that *"in case that any member declares conflict of interest concerning any matter under discussion, they will have no vote on the said matter"*,[35] the subsequent minutes of Committee meetings do not show any mention that any of its members would declare conflict of interest. In the available documents there is no mention of a conflict of interest on the part of Hana Cabrnochová, Roman Prymula or Roman Chlíbek, whose intense cooperation with vaccine producers will be mentioned later.

Furthermore, the Rules of Procedure of the National Advisory Committee on Immunization[36] say that "once in a year, the Chair, the Vice-Chair, the Secretary and the members of the Committee will make a statutory declaration, which will prove that that no decision taken by the Committee were to any member's benefit."

Neither do the minutes of the Committee mention who attended the meeting, who proposed the matters to be discussed, who made comments on particular matters and mainly who voted on them. Yet, this is rather crucial for public control over possible conflicts of interest.

The experts' activities within the framework of the National Advisory Committee on Immunization can be compared to the position of judicial experts, when presenting expert opinions to the court. Although judicial experts are required to have an objective approach due to the participants' right to a fair trial, with regard to the impact the Committee decisions have on public health and on health of individual children, the activities of the Committee members should be transparent and unbiased as well. As the Constitutional Court observed in its decision delivered on 25th June 2003, File No. II. ÚS 35/03, a reasonable doubt about an unbiased attitude of a judicial expert arises in cases of the expert's economic dependence on one of the parties, which means that *"it is not possible not to take into consideration the fact that the expert's approach to the expert opinion they prepare can be consciously or unconsciously affected by any feelings of solidarity or loyalty or by a fear of possible unfavourable professional and social impacts"*. According to the Constitutional Court such judicial expert has to be suspended in order to maintain the principles of fair trial.

It is clear that if we apply this principle, as interpreted by the Constitutional Court, then in cases of some of the Committee members there exists a reasonable doubt about their unbiased attitude. Therefore, in other words, these experts cannot be considered unbiased and independent.

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[34] http://en.wikipedia.org/wiki/Conflict_of_interest.

[35] See Point 1. of the minutes of the National Advisory Committee on Immunization meeting held on 31st March 2011. Available at (only in Czech): http://www.mzcr.cz/Verejne/Soubor.ashx?souborID=12283&typ=application/pdf&nazev=Z%C3%A1pis%20ze%20zased%C3%A1n%C3%AD%20NIKO%2031%203%202011%20pro%20web%20final.pdf

[36] The rules of procedure are available at (only in Czech): http://www.mzcr.cz/Verejne/obsah/jednaci-rad_2106_5.html.

Some professional associations and Committee members connected with pharmaceutical companies

It is necessary to mention two member societies of the Czech Medical Association of J. E. Purkyně, who have their representatives in the Committee and whose independence on pharmaceutical companies is open to reasonable doubt. And yet, in the media they often present themselves as independent professional societies that express independent professional opinions. In particular it is the Professional Society of Primary Care Paediatricians, member of CzMA and the Czech Vaccination Society, member of CzMA. Both societies are represented by Hana Cabrnochová, who is the Chair of the former society and the Vice-Chair of the latter one. More information on her activities will be provided further on.

In November 2011 the Czech Medical Association of J. E. Purkyně was asked to provide further information on the founding of the Czech Vaccination Society and of the Professional Society of Primary Care Paediatricians (who founded the societies, and when), as this information is not available at the websites of the respective societies. The CzMA refused to provide the requested information, although one would expect that the Association should act in a transparent manner in order to preserve the trustworthiness of itself as well as of its "daughter" societies.

Professional Society of Primary Care Paediatricians, member of CzMA

In case of the Professional Society of Primary Care Paediatricians, member of CzMA, it is sufficient to look at its website www.detskylekar.cz, which is shared with the Association for Primary Paediatric Care.[37] The website features logos of vaccine producers, advertisements for their vaccines and other one-sided promotional texts. On the contrary, we could not find any text that would deal with possible risks of vaccination, and the like.

On the website it is also mentioned that its principal partner is the pharmaceutical company GlaxoSmithKline, producer of the "compulsory" vaccines Infanrix Hexa and Priorix. Other partners are the pharmaceutical companies Pfizer and MSD (Merck Sharp & Dohme), vaccine producers as well.

The website also features advertising banners or links to websites of vaccine producers that provide highly biased information uncritically emphasizing the benefits of vaccines. These adverts and websites hold back any information on possible vaccine risks, the only warning being the suggestion to carefully read the patient information leaflet.

In particular, the website of the Professional Society features a Silgard banner, a vaccine produced by MSD, with the slogan "I decided to do the best I could". It remains to be answered whether it is not a misleading advertisement.[38] The website also features links to the following vaccines, their producers and their websites: Synflorix-Rotarix produced by GSK, with link to

[37] At the foot of the website you can read (only in Czech): „© 2010 Sdružení praktických lékařů pro děti a dorost ČR ve spolupráci s Odbornou společností praktických dětských lékařů ČLS JEP" ("Association for Primary Paediatric Care Czech Republic in cooperation with the Professional Society of Primary Care Paediatricians, member of CzMA"). However, the website of the CzMA provides a link to this website, which makes it clear that it is also the website of the Society.

[38] It can be very easily found that from the medical point of view, the cervical cancer incidence is greatly influenced by lifestyle, e.g. smoking, hygiene and sexual behaviour, therefore the advertising slogan, which can in one way be interpreted to mean that vaccination is all a woman can do in the way of prevention, can be considered misleading in the opinion of the author.

http://www.vakciny.cz, Prevenar produced by Pfizer, with link to http://www.prevenar.cz and Silgard – Rotateq produced by MSD, with link to the company website.

Although it is not clear whether the partnerships with the vaccine producers, and the presence of their adverts on the website, was established by the Professional Society of Primary Care Paediatricians or by the other web user, the Association for Primary Paediatric Care, we can assume that a professional society that cares for its independence and trustworthiness would never associate its website with advertisements for pharmaceutical company products.

However, we can assume that the association cooperating with vaccine producers is really the Professional Society of Primary Care Paediatricians, as the topic of vaccination is unambiguously connected with the Professional Society, once you start looking up further information about the Society and the Association. The advertising tone and the cooperation with vaccine producers become obvious if you click on the "Vaccination" section of the website. There is an absolute lack of expert articles, which can be found on the previously mentioned website of Marek Petráš, www.vakcíny.net. It mainly contains "pro-vaccination" texts of the following kind – instructions how to administer particular vaccines, documents provided by vaccine producers (e.g. statement made by GSK about the quality of the vaccine Priorix), promotional and advertising texts (promoting vaccination against cervical cancer and rotavirus), documents concerning vaccine distribution and related paperwork and procedures. However, there is no text that would point out the risks of promoted vaccinations, or that would promote a more moderate and individual approach to vaccination (e.g. in case of occurrence of adverse effects) or that would raise awareness on the part of parents.

The Professional Society of Primary Care Paediatricians, member of CzMA, is also one of the organizers of the yearly Primary Care Conference, which, considering this year's programme and partners, resembles more than anything else a marketing event of pharmaceutical companies. The principal partner of the conference organized in February 2012 was the GSK Company and main partners were the Pfizer and MSD Companies, and at the same time these companies held their own symposia with lectures given within their framework. On the first day of the conference, three out of seven symposia were held by vaccine producers.[39]

In 2009 the Professional Society of Primary Care Paediatricians helped the Ministry of Health disclaim the statement of an independent immunologist who appeared on TV and said that the use of hexa vaccine produced by GSK may be related to the increasing number of autistic children. On the following day, the Professional Society gave the Ministry an opinion in favour of GSK, stating that "the published information is not in accordance with scientifically proven facts", but not presenting any particular scientific findings.[40]

On the website you can also find a link to the Vox pediatriae magazine, which is, as the imprint says, issued by the Association for Primary Paediatric Care Czech Republic, with the expert supervision by the Professional Society of Primary Care Paediatricians. This magazine also contains many adverts for the above-mentioned vaccine.

[39] Information on the programme of the Primary Care Conference and its partners can be found on (only in Czech): http://ahou.cz/kongres.
[40] Statement about the hexa vaccine. Available at (only in Czech): http://www.detskylekar.cz/cps/rde/xchg/dlekar/xsl/z-tisku_28461.html.

It is not possible to find anywhere on the website the information about the income or other benefits the Professional Society gets from the adverts and partnership with pharmaceutical companies.

A striking contrast to the presentation of the Professional Society of Primary Care Paediatricians is the website of the Czech Pediatric Society, member of CzMA, http://www.pediatrics.cz, which features no advertisements at all. It contains only expert information, recommendations, opinions and information about education without any hint of cooperation with pharmaceutical companies. In spite of a meticulous search in newsletters up to ten years back no traces of such cooperation were found.

Czech Vaccination Society, member of CzMA

At first glance the website of the Czech Vaccination Society, member of CzMA, http://vakcinace.eu, there is no explicit sign of any cooperation with the pharmaceutical industry, as it is the case of the Professional Society of Primary Care Paediatricians website. You may merely notice a certain one-sidedness in articles that are in favour of introduction of new vaccines in the immunization schedule but do not contain any information about possible risks.

However, upon a more careful examination of the involved persons and other activities of this professional society, the connection with pharmaceutical companies becomes clearer. The Chair of the Society is Roman Prymula, the Vice-Chair is Hana Cabrnochová and the Secretary is Roman Chlíbek. According to the information provided in foreign magazines both the Chair and the Secretary have received remuneration from vaccine producers, which will be further dealt with below, as well as the activities of Hana Cabrnochová.

It is also worth mentioning that other members of the Committee are Jitka Částková, of the National Institute of Public Health and Vilma Marešová, of the University Hospital Na Bulovce, and one of the members of the audit committee is Jozef Dlhý, of the Ministry of Health. Six members of the Czech Vaccination Society are among the total of thirteen member of the National Advisory Committee on Immunization, which makes it a half if we count out the Chief Public Health Officer. This is a surprisingly high number, especially if we consider that the representatives of the above-mentioned neurological societies and representatives of the Czech Society of Allergology and Clinical Immunology have no place in the Committee.

In 2009 the Czech Vaccination Society together with the Professional Society of Primary Care Paediatricians helped the Ministry of Health disclaim the connection between the use of the hexa vaccine produced by GSK and the increasing number of autistic children (see above).[41]

News conference "What way is compulsory vaccination taking?"

In September 2011 a news conference entitled "What way is compulsory vaccination taking?" was held in Prague and officially organized by the Czech Vaccination Society in cooperation with a PR agency. However, by all appearances the conference was a media activity of GlaxoSmithKline, which did it in reaction to the current negative media image of the company.

[41] The press release of the Ministry of Health entitled „Reakce Ministerstva zdravotnictví ČR na informaci vysílanou ráno 26. 5. 2009 televizí Nova" ("Reaction of the Ministry of Health to the information aired in the morning of 26th May 2009 on TV Nova"), issued on 27th May 2009. Available at (only in Czech): http://www.mzcr.cz/dokumenty/reakce-ministerstva-zdravotnictvi-cr-na-informaci-vysilanou-rano-televizi-nova_1343_868_1.html.

Shortly before the conference was held, the Instinkt magazine published an article entitled "They're after your children, too", which pointed at the significant influence of vaccine producers upon the children immunization system in the Czech Republic, which is in contradiction with the children's interests. The article chiefly emphasized the following issues:[42]

- The possible serious adverse effects of the vaccines and their denial by doctors, the insufficient awareness among parents of the vaccine risks and of the risks from combination vaccines and simultaneous administration of more vaccines,
- A radically different approach to children vaccination in foreign countries, in which the vaccination is obligatory and it is the State that is responsible for possible adverse effects,
- Non transparent introduction of vaccinations in the Czech Republic and the conflict of interest on the part of the members of the National Advisory Committee on Immunization who collaborate with vaccine producers and recommend such procedures that are in contradiction with the interests of vaccinated children (preserving the hexa vaccine instead of selecting the pentavalent vaccine),
- The punishment of parents who have a different opinion on vaccination, the denial of preschool education to incompletely vaccinated children, the threat of forced vaccination against one's will, which will be provided for according to the draft act.

This article obviously was not in the interests of GSK, as the criticism contained in the article was aimed directly at the company and its business policy and it disclosed the company's influence upon the National Advisory Committee on Immunization and its decisions.

Within exactly two weeks the conference "What way is compulsory vaccination taking?" was organized under the patronage of the Chair of the Czech Vaccination Society, Roman Prymula, at whose personal connection to GSK the above-mentioned article pointed as well. The invitations also contained the Czech Vaccination Society logo.

Hana Cabrnochová made an appearance at the conference, acting as the Chair of the Professional Society of Primary Care Paediatricians, the Vice-Chair of the Czech Vaccination Society and also the Vice-Chair of the National Advisory Committee on Immunization and a paediatrician. Other appearances were made by Roman Chlíbek, acting as the Secretary of the Czech Vaccination Society and Head of the Department of Epidemiology of the Faculty of Military Health Sciences of the University of Defence and the Dean of the Faculty of the Military Health Sciences of the University of Defence, and by Ivan Novák, a paediatrician, who will not be further mentioned but who participated in the marketing activities of GSK.[43]

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[42] The Article entitled „Jdou i po vašich dětech" ("They're after your children, too"), published on 8th September 2011. Available at (only in Czech): http://instinkt.tyden.cz/rubriky/ostatni/jine/jdou-i-po-vasich-detech_26324.html.

[43] He repeatedly promoted vaccines produced by GSK and in the annual report on the company fund activities he is listed as a partner and collaborator. Sources (only in Czech): Article entitled „Pediatři udělali reklamu vakcíně" ("Paediatricians promoting vaccines"), published on 9th January 2003, on iDnes.cz, http://zpravy.idnes.cz/pediatri-udelali-reklamu-vakcine-d4a-/domaci.aspx?c=A030108_225233_domaci_was; annual report on the GSK company fund activities for 2009: http://www.nadacnifondgsk.cz/doc/vyrocni-zprava.pdf.

The conference was officially organized by AMI Communications, s. r. o., the biggest PR agency in the Czech Republic, which has connections to high politics and lobbying activities[44] and which, together with other companies connected by personnel and property, obtains significant contracts from multinational corporations and the most important state institutions. As far as the health care system is concerned, the company provides services for the VZP ČR (Czech Insurance Company)[45]; other companies connected with AMI Communications, s.r.o. provide services for the Ministry of Health[46] and pharmaceutical industry. However, this matter is not the subject of the present analysis.

The important thing is that GlaxoSmithKline is a steady client of AMI Communications, and the latter company provides the former company with following services: counselling, media relations, media preparation, employee relations, corporate social responsibility, organization of events.[47] In 2009 AMI Communications got an award from the Association of Public Relations Agencies for its services to GSK, in the category of Medicine/Pharmaceutics, in particular for the project of the European Cervical Cancer Prevention Week.[48]

Neither on the invitation to the news conference, which was sent to journalists, nor anywhere else did AMI Communications mention that GSK participated in any way in the organization of the event. Concealing the real client that ordered the event organization so that "the presentation would look like an exclusively professional event, which has nothing to do with a particular company" and that the company would get more attention in the media, this is nothing new – GSK was already criticized for a similar act in 2003.[49] The invitation to the news conference showed that the organizer was David Vondruška, an AMI Communications employee whose name often appears on GSK press releases.[50]

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[44] Jana Marco, a former deputy and spokesperson for ODS, has share in AMI Communications, founded in 1995. In 2002 Jana Marco together with Milan Hejl, Aleš Langr and Marek Stránský, also shareholders of AMI Communications, founded lobbying firm PAN Solutions, s. r. o. and other companies.
Source (only in Czech): http://ona.idnes.cz/snemovna-plna-zen-by-nicemu-nepomohla-rika-byvala-poslankyne-jana-marco-1nt-/spolecnost.aspx?c=A091113_151407_ona_ony_jup; the Trade Register.

[45] According to the Information system for public contracts the AMI Communications Company acquired the following contracts from VZP ČR (an insurance company): Prevention of overweight and obesity in 2010, a sum of 14,650,000 CZK excluding VAT, Prevention of overweight and obesity in 2008, a sum of 16,805,882 CZK excluding VAT, Internal communication within VZP ČR in 2007, a sum of 2,520,000 CZK excluding VAT, Support of health and healthy lifestyle aimed at fight against obesity in 2007, a sum of 5,000,000 CZK excluding VAT. Available at (only in Czech):
http://vz.statnisprava.cz/?sid=0&pg=dod4zad&idm=94206&idd=101326.

[46] See the contract for "preparation of communication strategy concerning changes in the health care and for provision of professional consulting and counselling activities in the course of implementation of the said strategy" between the Ministry of Health and CivCom, s.r.o., negotiated remuneration: 1,560 CZK including VAT per hour. The company CivCom, s. r. o. was represented by executive director Marek Stránský, who is also the executive director of AMI Communication. The contract is available on the Ministry of Health website (only in Czech): http://www.mzcr.cz/dokumenty/mz-cr-x-civcom-sro_4778_2334_1.html.

[47] http://www.amic.cz/nase-sluzby/reference/?showDetail=41.

[48] http://www.amic.cz/o-spolecnosti/oceneni/.

[49] http://zpravy.idnes.cz/pediatri-udelali-reklamu-vakcine-d4a-/domaci.aspx?c=A030108_225233_domaci_was.

[50] E.g. the press release entitled „Incidence invazivních pneumokokových onemocnění (IPO) u dětí do pěti let se v ČR stále drží na nízké úrovni" ("Incidence of invasive pneumococcal disease (IPD) in children up to five years of age is still low in the Czech Republic"), issued on 15th June 2011, available at (only in Czech):
http://www.gsk.cz/pro-novinare/zpravy/incidence-invazivnich-pneumokokovych-onemocneni.html;

Because of the news conference the League of Human Rights has filed a report to the State Institute for Drug Control for a possibly unlawful hidden advertisement or for a possibly unlawful advertisement for medicinal products for human use available on prescription. However, the Institute decided not to launch administrative proceedings.[51]

A representative of the Rozalio association, which focuses on enforcing freedom and raising awareness of children vaccination, also wanted to participate in the conference and submitted an official application on behalf of the organization. However, the organizer David Vondruška refused her, saying that the news conference is intended exclusively for journalists, although he had accepted several representatives of the public who did not even have to state whether they work for media or not. The Rozalio association issued a press release concerning the event, in which they assumed that the news conference was a PR activity of GSK, and in which they questioned the impartiality of the lectures and accused AMI Communications of violation of PR agency ethical code.[52]

After the news conference the agency AMI Communications sent a summary of the conference in the form of a fictitious interview to the media on behalf of the Czech Vaccination Society.[53] The text was obviously a reaction to the questions that were raised in the above-mentioned article, "They're after your children, too", published in the Instinkt magazine. The text of the media reaction contained much information that was supposed to convey the impression that the compulsory vaccination should be preserved and the parents' decision-making competence should be restricted and to persuade the public of the safety of the polyvalent vaccine, early vaccination of newborns, vaccination of slightly ill children and simultaneous vaccination with multiple vaccines. Yet even the experts cannot reach an agreement on those issues.

For example, without providing any evidence the text states that even in those countries, in which vaccination is voluntary, there are laws that govern vaccination in the form of indirect duty which means that unvaccinated children are not allowed in groups of children. However, there was no mention about the particular countries, nor was there any evidence supporting the simplistic statement. On the contrary, according to our findings in our neighbouring countries – Austria and

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the press release entitled „Rodiče mohou do konce roku ušetřit na očkování svých dětí proti rotavirům" ("Parents can save money on children vaccination against rotaviruses until the end of the year"), issued on 11th April 2011, available at (only in Czech): http://www.gsk.cz/pro-novinare/zpravy/rodice-mohou-do-konce-roku-usetrit-na-ockovani.html.

[51] A notification of the State Institute for Drug Control issued on 18th October 2011, File No. Sukls184549/2011. Report was submitted with reference to the decision of the Court of Justice of the European Union delivered on 2nd April 2009, File No. C-421/07 in the case of Damgaard, according to this decision the act of passing on information about a drug by a third party on the third party's own initiative can also be considered as advertising. It was then pointed out that even if it were not possible to prove the existence of a connection between GSK and the lecturers, the lecturers' activities could still be considered as unlawful advertising by the authorities.

[52] The press release of the Rozalio association entitled „Kdo se schovává za povinné očkování?" ("Who's hiding behind compulsory vaccination?"), issued on 22nd September 2011. Available at (only in Czech): http://www.rozalio.cz/index.php?option=com_content&task=view&id=442&Itemid=146.

[53] Source (only in Czech): http://www.naseporodnice.cz/clanek-20-nejcastejsich-otazek-a-odpovedi-k-detskemu-ockovani-1-cast.php; http://www.tribune.cz/clanek/24106.

Germany – parents are not sanctioned, either directly or indirectly, for making decisions on vaccination.[54]

Hana Cabrnochová

As we have already mentioned, Hana Cabrnochová is the Chair of the Professional Society of Primary Care Paediatrician, member of CzMA, the Vice-Chair of the Czech Vaccination Society, member of CzMA, and the Vice-Chair of the National Advisory Committee on Immunization. Since 1995 she has run an independent paediatric practice and since 2001 she has acted as the Chair of the Professional Society of Primary Care Paediatricians, member of CzMA.[55] She is married to Milan Cabrnoch, who used to work as a paediatrician as well, and who now is a politician for ODS (Civic Democratic Party) and Deputy of the European Parliament, and whose connection with the project of the controversial electronic medical record books IZIP is the current topic for discussion.[56]

Hana Cabrnochová is also the member of the Central European Vaccination Advisory Group (CEVAG), which is aimed at promoting collaboration among physicians from Central Europe. In the 2005 Group newsletter you can read the phrase "advocating vaccination for all" and at the end of the document you can read that it was sponsored by GlaxoSmithKline, a vaccine producer. On the CEVAG website it is also mentioned that it is sponsored by Pfizer, a vaccine producer.

Publishing activity

Considering the important functions that Hana Cabrnochová carries out, she does not publish nearly as many expert articles as her colleagues do. For example, on the foreign website associating expert articles, pubmed.gov[57], there is no expert article written by her, although her colleagues from the National Advisory Committee on Immunization or from the Czech Vaccination Society have several articles published there (Prymula, Chlíbek, Dlhý, Částková, Vančíková, Trmal).

The texts by Hana Cabrnochová are rather informative and limited to a description of the immunization schedule and the number of vaccinated children, to promotion of implementation of new vaccines made by cooperating vaccine producers, the work of the National Advisory Committee on Immunization, and to the legal aspects of vaccination.[58]

Her articles and presentations are typically emphasizing the effects and safety of vaccines and lacking any mentions of risks[59], some of them may even be considered to contain misleading infor-

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[54] Legal systems of children vaccination – analysis of legal regulations in selected European countries. The League of Human Rights, 2010. Available at (only in Czech): http://llp.cz/wp-content/uploads/Pravni_systemy_ockovani_deti1.pdf.

[55] Biography available at (only in Czech): http://www.rozhlas.cz/leonardo/anonce/_zprava/191482.

[56] E.g. article entitled „Zdravotnictví jako obchod, kočíruje ho skupinka v ODS" ("Health care as a trade, governed by a group of people in the ODS"), published on 23rd March 2012, in Lidové noviny, available at (only in Czech): http://www.tribune.cz/clanek/26118-zdravotnictvi-jako-obchod-kociruje-ho-skupinka-v-ods.

[57] http://www.ncbi.nlm.nih.gov/pubmed/ - PubMed comprises more than 21 million citations for biomedical literature from MEDLINE, life science journals, and online books. Citations may include links to full-text content from PubMed Central and publisher websites.

[58] http://www.pmfhk.cz/WWW/HVD_2010.htm;
http://www.prolekare.cz/cesko-slovenska-pediatrie-clanek?id=26542&confirm_rules=1;
http://www.vakciny.net/AKTUALITY/11.narodni%20ockovaci%20den%20CR.pdf;
http://www.zdn.cz/clanek/postgradualni-medicina-priloha/ockovani-kojencu-460177.

[59] The only exception was when she was supporting the abolition of global vaccination of newborns against TB (www.cpsjep.cz/cz/dokumenty/TBC.doc). Together with others she pointed at serious side effects of the

mation on the effectiveness of or indications for vaccination, although it may be expected that medical ethics mean presenting both pros and cons:

In her article entitled ***„Proti kterým nemocem je vhodné vaše dítě očkovat" ("Which diseases should your children be vaccinated against?")***[60], published in 2011, Hana Cabrnochová presents seven optional vaccinations including the prices of vaccines. Among others she promotes vaccination against chicken pox produced by GlaxoSmithKline:

"Available vaccines against measles, rubella, mumps and chicken pox (Priorix Tetra). It is administered in two doses and it can be used instead of the compulsory vaccination against measles, rubella and mumps only, therefore it is not necessary to administer further injections if you want to protect the child against chicken pox as well. So the child is protected already at the age, at which they can encounter chicken pox among other children. The two-dose vaccination against chicken pox is nowadays recommended for individual vaccination as well (Varilrix vaccine). The price for one dose of Priorix Tetra is about 1,600 CZK. The price for one dose of Varilrix is about 1,400 CZK. "

She completely fails to mention the crucial fact that the Varilrix vaccine against chicken pox is not indicated for the majority of healthy children according to the review of information on medicinal product.[61] The indication is limited to those healthy individuals who get in close contact with patients who are supposed to suffer or who suffer from severe progression of the disease. Otherwise, the conditions of indication are not met and the administration of the vaccine in healthy children, in whose family there is no one with expected severe progression of the disease, is non lege artis. However, the quoted text creates the impression that the vaccine is suitable for all healthy children.

Hana Cabrnochová does not mention the vaccine risks at all, although these are in no way inconsequential. It has been scientifically proven that the tetravalent vaccine, which moreover contains a component against chicken pox (MMRV – in this case it is Priorix Tetra), involves a greater risk that the commonly used trivalent vaccine against measles, mumps and rubella (MMR). In particular, the risk of an adverse effect in the form of febrile seizures is twice as high.[62]

In an online article entitled ***"Nepovinná očkování" ("Optional vaccinations")***[63], published in 2008, Hana Cabrnochová recommends a simultaneous administration of Prevenar and a hexa vaccine on one day and on different body parts, although in independent experts' opinions, for example Marek Petráš's, this procedure is considered to pose a greater risk for the child.[64]

In her presentations entitled ***„Současná situace v očkování dětí a adolescentů v České republice 2007" ("The current situation concerning vaccination of children and adolescents in 2007")***[65]

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vaccine. However, it is interesting to note that the vaccine in use is produced by a pharmaceutical company, which is not on the list of partners of her professional society.

[60] http://cabrnochova.cz/media/ockovani-2011.pdf.

[61] Review of information on Varilrix, revision date: 12th January 2011, available at (only in Czech): http://www.sukl.cz/download/spc/SPC13310.pdf.

[62] See the article by Marek Petráš entitled „Rizikovější očkování vakcínou MMRV?" ("A greater risk of vaccination using the MMRV vaccine?"), published on 6th September 2010, available at (only in Czech): http://vakciny.net/AKTUALITY/akt_2010_22.htm, which was based on an article published in Pediatrics on 28th June 2010.

[63] http://www.cabrnochova.cz/i-nepovinna-ockovani.html.

[64] Reply to an e-mailed question sent on 22nd August 2010.

[65] http://cabrnochova.cz/media/070303kpp.pdf.

and ***„Novinky v očkování 2006" ("News on vaccination in 2006")***[66] she introduces the vaccines Varilrix, Prevenar, Rotarix and Cervarix produced by GlaxoSmithKline and Pfizer. It is worth mentioning that she describes chicken pox in very dramatic words *("highly contagious"*, *"varicella is not a banal disease"*, the use of a sad smiley face with blisters), only to offer a solution in the form of the Varilrix vaccine by GSK, accompanied by a happy smiley. Again she forgets to mention that this vaccine is not indicated for normal healthy children, creating just the opposite impression (see above). She never mentions the risks of the vaccine. She refers to the GSK promotional websites, www.nestovice.cz, www.ctyrijednouranou.cz, which promote vaccination against chicken pox in a manipulative manner.

In the above mentioned 2007 presentation she also gives misleading information on the HPV infection – among the reasons for global vaccination of adolescents she quotes "*100 per cent effectiveness"*. And all this while in 2010 GSK was given a fine of 500,000 CZK by the final judgement of the State Institute for Drug Control for claiming a "100% effective vaccine" and other misleading information, which was not consistent with the review of information on Cervarix, in their promotional materials.[67] Once again, Hana Cabrnochová does not mention any risks either of the mentioned vaccination or of other vaccinations she promotes in the presentation. The presentation on "Vaccination against HPV" she gave at the seminar concerning ***"The issue of cervical cancer"*** held in the Chamber of Deputies was much the same.[68]

In an online article entitled ***„Hexavakcína ušetří sedm očkování" ("Hexa vaccine can spare children seven vaccinations")***[69] published in 2007 she mentions the supposedly more tolerable vaccine Infanrix Hexa produced by GSK. However, the experts' opinions differ as to whether it is not better for children to be vaccinated against each disease with separate vaccines or with a lesser number of vaccines combined.

In an online article entitled ***„Pohled pediatra na očkování proti rotavirům" ("A paediatrician's view on vaccination against rotaviruses")***[70] she promotes vaccination against rotaviruses with the vaccine Rotateq produced by MSD; she recommends vaccination for all children with the exception of contraindications.

Promoting GlaxoSmithKline

Hana Cabrnochová has also repeatedly engaged in promotional activities for GlaxoSmithKline aimed at promoting vaccination and has acted as a respected expert – being the Chair of the Professional Society of Primary Care Paediatricians, member of CzMA. Recently she has made an appearance at the news conference "What way is the compulsory vaccination taking?", which was, by all accounts, organized by GSK (see above).

In the past years she has also repeatedly given lectures at the Primary Care Conference[71] within the framework of the symposium on vaccination held by GlaxoSmithKline. For example, in 2011 the topic was the news on children vaccination, and she promoted vaccines produced by this company

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[66] http://cabrnochova.cz/media/ockovani_Praha%20kongres.pdf.
[67] Information obtained following a request submitted to the State Institute for Drug Control (Information provided on basis of a request submitted on 9th December 2011, File No. Sukls145618/2011).
[68] http://cabrnochova.cz/media/HPV-Parlament-CR-240709.pdf.
[69] http://www.cabrnochova.cz/t-ln-hexavakcina-070109.html.
[70] http://cabrnochova.cz/t-ockovani-proti-rotavirum.html.
[71] http://www.tribune.cz/clanek/21844; http://www.tribune.cz/clanek/16860-pestry-vejir-vakcin-a-vahavicesi.

and she spoke in favour of introduction of other optional vaccinations in the children immunization schedule, while failing to mention or making light of possible risks (pneumococcus, rotaviruses). She defended vaccination against chicken pox and the use of tetravalent vaccines produced by GSK, which contain this component, regardless of the fact whether the child is indicated for vaccination or not, as it is necessary for administering the individual vaccine against chicken pox.

She also gives opinions in press releases submitted by GSK. In 2010 and 2011 she spoke in favour of vaccination against cervical cancer.[72]

In 2003 Hana Cabrnochová, acting as the Chair of the Professional Society of Primary Care Paediatricians, took under her auspices the news conference, at which she recommended the new vaccine produced by GlaxoSmithKline. According to the information in the media, this was basically an advertisement for a new vaccine two-and-a-half times more expensive that the one currently in use. The media also claimed that *"the presentation looked like an exclusively professional event, which has nothing in common with a particular company"* and that *"the organizing agency never mentioned that the main organizer and sponsor of the whole event was GlaxoSmithKline."* This was supposed to bring the company more media publicity. The then President of the Czech Medical Chamber David Rath made a comment: *"It is sheer publicity. Doctors let themselves be dragged into the competition between companies."* In reaction Hana Cabrnochová said: *"We take under our auspices such events that are beneficial to children. We would never promote something that is only comparable."*[73]

Roman Prymula and Roman Chlíbek

Unlike Hana Cabrnochová Roman Prymula and Roman Chlíbek are experts, who have many articles published in foreign magazines. However, some articles contain their declarations of conflict of interest, which show their close connections to vaccine producers. Such articles and studies are also sponsored by vaccine producers, mainly by GlaxoSmithKline. Moreover, they both support the company marketing activities.

According to the brief declarations of conflict of interest Roman Prymula has been a long-term advisor and member of advisory boards of the GSK Company, from which he receives remunerations for counselling and other financial compensations. He also carries out a regular research, which is sponsored by the company. He has also received remuneration for his collaboration with Wyeth, Baxter, Aventis Pasteur, Novartis and MSD.[74]

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[72] http://www.gsk.cz/pro-novinare/zpravy/ockovani-bude-dostupne-pro-vice-zen.html; http://www.gsk.cz/pro-novinare/zpravy/evropsky-tyden-prevence.html.

[73] http://zpravy.idnes.cz/pediatri-udelali-reklamu-vakcine-d4a-/domaci.aspx?c=A030108_225233_domaci_was.

[74] Information on remunerations and collaboration with pharmaceutical companies can be found among others in these articles:

- Rubella revisited: Where are we on the road to disease elimination in Central Europe? Vaccine, Volume 29, Issue 49, 15 November 2011, Pages 9141-9147.
- Impact of the 10-valent pneumococcal non-typeable Haemophilus influenzae Protein D conjugate vaccine (PHiD-CV) on bacterial nasopharyngeal carriage. Vaccine, Volume 29, Issue 10, 24 February 2011, Pages 1959-1967
- Safety and Immunogenicity of the HPV-16/18 AS04-Adjuvanted Vaccine: A Randomized, Controlled Trial in Adolescent Girls. Journal of Adolescent Health, Volume 46, Issue 5, May 2010, Pages 414-421

For Roman Chlíbek, too, it is possible to look up the information about his collaboration with pharmaceutical companies – he is a counsellor and a collaborator of the GSK Company, for which he conducts research and from which he receives remuneration and financial compensation. He also cooperates with Baxter, Novartis, Aventis Pasteur and Pfizer and receives financial support from some of the companies for his participation in scientific conferences.[75]

Both experts declare conflict of interest only in those articles that are published in foreign magazines, as it is obligatory there. However, they do not declare any conflict of interest as far as their domestic activities are concerned, especially their activities as members of the National Advisory Committee on Immunization, and their promotional activities in favour of pharmaceutical companies, nor is it possible to find such declarations in the available professional papers of the Czech Vaccination Society, or in the statements published in the media. Being engaged in these activities, both experts act as completely independent and unbiased experts.

A recent example of such activities was the Primary Care Conference held in February 2012, at which Roman Chlíbek delivered a speech, acting as a seemingly independent expert, while not mentioning the fact that he receives remunerations and other financial benefits from vaccine producers. There, at the symposium on vaccination held by GlaxoSmithKline he made an appearance, acting as the Secretary of the Czech Vaccination Society, member of CzMA. He talked about the role of advisory boards and about the process of creation of professional recommendations concerning vaccination. He also talked about the activities of the Czech National Advisory Committee on Immunization, which he presented in a positive way as an independent multidisciplinary body established in accordance with the recommendation of the World Health Organization. He emphasized its independence by saying that each member declares conflict of interest prior to every meeting.[76]

In 2009 Roman Chlíbek published a guidebook entitled "Best practice in vaccine administration and non standard situations" for GSK. There he recommends certain procedures for vaccination "to the best knowledge of the authors". Among others the guidebook recommends vaccination of a child who suffers from a mild acute infectious disease accompanied or not by a raised tempera-

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- Effect of prophylactic paracetamol administration at time of vaccination on febrile reactions and antibody responses in children: two open-label, randomised controlled trials. The Lancet, Volume 374, Issue 9698, 17-23 October 2009, Pages 1339-1350.
- Prevention of otitis media: Now a reality? Vaccine, Volume 27, Issue 42, 25 September 2009, Pages 5748-5754.
- Pneumococcal serotype 3 otitis media, limited effect of polysaccharide conjugate immunisation and strain characteristics. Vaccine. Volume 27, Issue 24, 21 May 2009, Pages 3213–3222.
- Kinetics of the immune response following pneumococcal PD conjugate vaccination. Vaccine, Volume 25, Issue 11, 1 March 2007, Pages 1953-1961.

[75] Information on remunerations and collaboration with pharmaceutical companies can be found among others in these articles:

- Rubella revisited: Where are we on the road to disease elimination in Central Europe? Vaccine, Volume 29, Issue 49, 15 November 2011, Pages 9141-9147.
- Effect of prophylactic paracetamol administration at time of vaccination on febrile reactions and antibody responses in children: two open-label, randomised controlled trials. The Lancet, Volume 374, Issue 9698, 17-23 October 2009, Pages 1339-1350.

[76] Article entitled „NIKO připravila doporučení pro rok 2012" ("NIKO's recommendations for 2012"), published on 27th March 2012, in Medical Tribune. Available at (only in Czech): http://www.tribune.cz/clanek/26164-niko-pripravila-doporuceni-pro-rok.

ture.[77] However, according to the opinion of Marek Petráš, an independent expert, every vaccination should be given, when the child is in good physical condition, and does not suffer from cough, cold, fever, fatigue and upset in order to avoid possible severe adverse effects of vaccination.[78]

It is not possible to find the actual sums both experts received from pharmaceutical companies, as they are not obligated to publish this information in their declarations of conflict of interest for foreign magazines. However, the amount of these remunerations is crucial for assessing to what extent these persons are economically dependent on a certain pharmaceutical company, and to what extent they can, therefore, be influenced by any feelings of solidarity and loyalty in their further activities.

Suspicious Committee recommendations in the interests of pharmaceutical companies

Looking through the minutes of the Committee meetings, it becomes clear that some of the recommendations and views given and expressed by the Committee can create an impression that they are adopted in the interest of some pharmaceutical companies and against the interest of vaccinated children.[79]

Criticism of thorough system for reporting adverse effects of vaccines

On its meeting held on 3rd November 2010 **the Committee criticized the practice of thoroughly filed reports on adverse effects following vaccinations**, as the State Institute for Drug Control (hereinafter "SUKL") "requires that every reaction including one, which is not necessarily related to vaccination should be reported." The Committee commented on this, saying that "the assessment of such reports is problematic, as in some cases the expected reactions are reported as well." That is why the Committee invited the director of the SUKL to their next meeting.

It is obviously against the interests of vaccinated children if the Committee questions the practice of reporting all reactions, including the ones not necessarily related to vaccination. After a new vaccine is approved, some of the side effects that appeared in the course of vaccine testing are listed in the review of information on the medicinal product. However, it is only after the release of the vaccine to the market and on basis of the reports on all reactions to vaccination that it is possible to reveal any rare or severe side effects, which could not have been revealed in the course of the vaccine testing prior to registration. On basis on these findings the vaccine safety may be reassessed and subsequently, the vaccine may be withdrawn from the market. Properly documented and repeatedly occurring side effects may also help the affected persons prove the causal link between vaccination and harm to health, and obtain damage compensation. If the Committee tries to prevent the ascertainment of complete and exact information on side effects of vaccines, they act in the interests of the vaccine producers.

Preventing the use of other than officially determined vaccines

The Committee tries to prevent paediatricians and parents from using other that those vaccines that are determined by the State, although other vaccines may be more suitable and involving less risk for children:

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[77] Chlíbek, R., Smetana, J. Správná očkovací praxe a nestandardní situace. Praha: Grada Publishing, 2009, s. 26. Available at (only in Czech): http://www.mediforum.cz/pdf/ockovaci-praxe-nadstandartni-situace.pdf.
[78] Reply to an emailed question sent on 22nd August 2010.
[79] Minutes and views of the National Advisory Committee on Immunization are available at (only in Czech): http://www.mzcr.cz/Verejne/obsah/narodni-imunizacni-komiseniko-_1983_5.html.

On its meeting held on 6th September 2011 **the Committee criticized the vaccination centre of the University Hospital v Motole for replacing the vaccine Priorix produced by GSK by a vaccine produced by other company (Trivivac by Sevapharma)**. The Committee questioned the professional procedure of the vaccination centre experts who recommend an alternative vaccine for children suffering from egg allergy and it also questioned the fact that egg allergy is an actual contraindication for administering the Priorix vaccine. However, the Committee gave no scientific reasons for their opinion and it remains to be answered whether this was not a case of interference with safe medical procedures, which would be in contradiction with the interests of the vaccinated children. A more proper action in such case would be to initiate further professional discussion and to give unambiguous professional reasons for the Committee's opinion.

On its other meeting held on 8th November 2011 **the Committee rejected a request submitted by the Sanofi-Pasteur Company who asked the Committee to add their vaccine among the medicinal products used in the immunization schedule, as an alternative to the vaccine in use, Infarix.** By doing so, the Committee has made GSK the exclusive supplier, although they admitted that in the future they may classify their vaccine as an alternative. Paediatricians and parents are, therefore, prevented from using an alternative insurance-covered vaccine, although this might be a more suitable option for the child.

On the same meeting the Committee tried to prevent the parents and paediatricians from choosing to have the vaccination administered in several doses rather than to use the hexa vaccine (several mono vaccines or a lesser number of vaccines combined). The Committee suggested that health insurance companies should carry out checks on doctors and if they find an "extremely high consumption" of less valent vaccines, they should ask for a medically valid reason based on medical documentation. The Committee decided that health insurance companies will not cover less valent vaccines used only upon the request of parents. This is yet another example of interference in the paediatricians' and parents' right to select such vaccination that they think is the best.

Preserving hexa vaccine instead of introducing a more tolerable pentavalent vaccine

On its meeting held on 3rd June 2011 **the Committee did not recommend the replacement of the hexa vaccine (Infanrix Hexa produced by GSK) by a cheaper and more tolerable pentavalent vaccine without the component against Hepatitis B**. Yet the global vaccination of newborns against Hepatitis B has been criticized by many independent experts and the above mentioned study conducted by the National Institute of Public Health was strongly against it prior to the vaccination introduction. The preservation of hexa vaccine instead of the introduction of pentavalent vaccine is obviously in the interest of vaccine producers, who get higher income from selling more expensive vaccines.

Recommending vaccine containing component against chicken pox in spite of lack of indication

On its meeting held on 3rd June 2011 **the Committee recommended the use of the commercial vaccine Priorix Tetra produced by GSK, although its component against chicken pox is not indicated in healthy children from healthy families**. The GSK Company also supplies a separate vaccine against chicken pox (Varilrix); in the review of information on this vaccine it is given that it should only be administered to children who are likely to suffer from severe consequences of the disease or who have a family relative who is likely to suffer from severe consequences. It explicitly

states that in healthy children "the purpose of the vaccination is to reduce the risk of disease transmission through a wild-strain varicella among these persons."[80]

If this component with very restricted indication is included in the tetravalent vaccine Priorix Tetra (although there is no restriction on indication), then it is obvious that this vaccine is not indicated for healthy children, too, and that administering the component against chicken pox is a non lege artis procedure that is in contradiction with the interests of the child. This would mean that a healthy child from a healthy family, who was given a non indicated vaccine, would be exposed to its risks without it being proven and approved that the vaccine benefits are more significant than its risks.[81]

Opinions questioning supposedly untrue information on vaccine risks

The National Advisory Committee on Immunization has protested against the opinions of independent experts who are warning about the risks of the vaccine against cervical cancer. According to the Committee's opinion, the co-author of the book entitled "Doba jedová" ("Poison Age"), the neuropharmacologist Anna Strunecká, presents untrue information about fatal cases occurring after administration of HPV vaccine, which she passes for information provided by experts on vaccination. The Committee says that her statements are not "based on scientifically reliable sources". However, in its opinion the Committee does not refer to any scientific sources, either. The Committee merely states in general that the vaccines have been submitted to clinical trials and their safety has been proved many times.

Conclusion and recommendations

Criteria for assessing and accounting for changes in vaccination system

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.

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[80] Review of information on Varilrix, revision date: 12th January 2011, available at (only in Czech): http://www.sukl.cz/download/spc/SPC13310.pdf.

[81] "The obvious advantage of the vaccination is the protection against the disease and its spread, while its disadvantage is the risk of adverse effects and complications. The assessment of the importance of vaccination against a particular disease requires the knowledge of both – the disease and the vaccine, i.e. the risk of the disease development and related risks as well as the advantages and disadvantages of the vaccine itself." Örtqvist, Å. Vaccination of children – a systematic review. Acta Pædiatrica ISSN 0803–5253, 99/2010 (Suppl. 461), p. 6.

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:[82]

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:

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.

Satisfactory resolution of conflict of interest

According to the available materials, the current resolution of the conflicts of interest in the National Advisory Committee on Immunization is absolutely insufficient. The members are supposed to voluntarily declare a conflict of interest, and subsequently they are excluded from the discussion on a certain issue. However, based on the available materials, it is not possible to find out whether any of the members has ever done so, or else the information is not publicly available. Neither of the options is acceptable. Once a year the Committee members also sign a document stating that they did not receive any benefit as a result of the decisions made.

Neither is publicly available the information on the attendance of each member and on their activities in the course of discussions on particular issues. The published materials merely mention the opinion of the Committee as a whole.

The Committee members do not have any obligation to clarify their relationships with vaccine producers, they do not have to say whether they or their professional societies receive any remu-

[82] Örtqvist, Å. Vaccination of children – a systematic review. Acta Pædiatrica ISSN 0803–5253, 99/2010 (Suppl. 461), p. 10.

nerations or other benefits from the pharmaceutical companies, they do not even have to say whether and in what way the collaborate with the companies.

There are many foreign professional papers containing strategies and methods of resolving a conflict of interest in the medical field. For example, the American Institute of Medicine issued a detailed publication about the conflict of interest containing three complementary supports – disclosing, managing and restricting.[83]

On basis of these principles it is possible for the National Advisory Committee on Immunization to adopt a well-balanced and responsible strategy for resolution of conflicts of interest in order to make its decision-making more unbiased, independent and trustworthy, and to include all significant groups and experts in the decision-making and effective cooperation. Such strategy should be obviously published, too.

In our circumstances it is impossible to imagine that all experts who ever collaborated with vaccine producers and who get any remuneration from them would be automatically ruled out as possible Committee members. Then again, it is certainly necessary to forbid the membership of such persons whose collaboration with and financial dependence on pharmaceutical companies goes beyond the acceptable extent. The needed experts, who should be ruled out as Committee members due to a conflict of interest, could possibly be invited to the Committee meetings as external experts with an advisory vote.

In order to make the work of the Committee more transparent and trustworthy, it should be obligatory to disclose a certain appropriate amount of information about the Committee activities, including the biographies of the Committee members, facts about the collaboration between the Committee members or their respective professional societies and the pharmaceutical companies, which could raise suspicion as to a possible conflict of interest. It should also be obligatory to disclose information about who attended the Committee meetings, who proposed a certain matter for discussion, who made any comments on it, and especially who voted for and who voted against. It could also be made obligatory to publicly declare a possible conflict of interest, making the provision of untrue or incomplete information sanctioned – if only by terminating the membership in the Committee.

Well-balanced composition of the Committee

The National Advisory Committee on Immunization should be a well-balanced authority composed of independent and respected experts in different fields, including those who have a more critical approach to vaccination and who are concerned with adverse effects of vaccines – immunologists, allergologists, neurologists, etc. When appointing a Committee member, the emphasis should not be put on the number of representatives of certain professional societies, but it should be put on the professional, personal and moral qualities of every member and on their contribution to the Committee work.

It would also be beneficial to the Committee work if there were non-professional representatives, such as parents associated in civic societies focusing on vaccination, or representatives of an independent and trustworthy body, for example the Office of the Public Defender of Rights or the Government Commissioner for Human Rights. They would undoubtedly make the Committee work

[83] Conflict of Interest in Medical Research, Education, and Practice. Institute of Medicine. 2009. Available at: http://www.iom.edu/Reports/2009/Conflict-of-Interest-in-Medical-Research-Education-and-Practice.aspx.

more transparent and put emphasis on provision of comprehensible information and on the best interests of children.

Responsibility for adverse effects of vaccines

So far the State has not assumed the responsibility for adverse effects of vaccines, which the State determines as obligatory or recommends and covers as optional. Yet, it is common in Western European countries that the State assumes responsibility for ordered or recommended vaccines.[84]

By doing so, the State shifts the objective civic responsibility for adverse effects of vaccines to doctors who administer the vaccine. However, the doctors have a legal obligation to administer the vaccine and liability may occur even if the vaccine is administered correctly. At the same time, the same doctors are obligated to watch and report any side effects of vaccines. Therefore, it is not surprising that the number of reports on side effects of vaccines filed in the Czech Republic is very low and no one has ever been awarded compensation for health damage caused by vaccination. Yet, it is proved that eight newborns died in consequence of vaccination against tuberculosis. This means that there is a substantial discrepancy in the legal relations concerning vaccination.

The new Civil Code, which will come into effect on 1st January 2014, revokes the afore mentioned kind of responsibility and the affected persons will be able to get compensation only in case it is proved that the doctor committed any error. However, if the person's health is damage without any error committed by the doctor, then the affected person will face considerable difficulties in obtaining any compensation from the State, as the Act No. 82/1998 Coll., on liability for damage caused in the course of exercise of public power by decision or incorrect procedure of authorities, does not apply in this case. Ordering vaccination cannot be considered as an incorrect procedure of authorities. At the same time, the State has never officially assumed responsibility for adverse effects of vaccination of children, as it did in 2009 on the occasion of an exceptional vaccination against swine influenza.[85]

Such state, in which the legal regulations concerning obligatory vaccination order individuals to undergo a possibly harmful intervention in their personal integrity in the interest of other persons' protection and, at the same time, fail to provide for compensation for such consequence, can be considered as an inappropriate intervention in the individual rights and such legal regulations can be considered as anti-constitutional. At least, such was the decision of the Constitutional Court of Italy, which has repeatedly confirmed by its decisions that the State is objectively responsible in case that the affected person underwent an obligatory vaccination for the reasons of public health protection, and subsequently suffered an unexpected and uncaused harm.[86] Following these decisions the Italian government introduced the Act No. 210/1992 G. U., on compensation to individuals suffering from irreversible complications as consequence of obligatory vaccinations and transfusions.

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[84] Legal systems of children vaccination – the analysis of legal regulations in selected European countries. The League of Human Rights, 2010. Available at (only in Czech): http://llp.cz/wp-content/uploads/Pravni_systemy_ockovani_deti1.pdf.

[85] Press release of the League of Human Rights entitled „Před odpovědností za vakcínu lékaře neochrání ani reverz" ("A signed discharge against medical advice cannot absolve doctors from responsibility for vaccination"), issued on 26th November 2009. Available at (only in Czech): http://llp.cz/2009/11/pred-odpovednosti-za-vakcinu-lekare-neochrani-ani-reverz.

[86] Decisions of the Constitutional Court of Italy No. 118 delivered in 1996, No. 258 delivered in 1994 and No. 307 delivered in 1990.

However, it remains to be answered whether the vaccine producers that supply the state-ordered vaccines should not be made partly responsible for possible adverse effects, and therefore should not participate in compensating the affected persons. Today, the vaccine producers have a certain income from vaccine selling, yet they bear no responsibility for their products, except for the responsibility for damage caused by a defective product. However, given the strict legal regulations, it is even harder to imagine that this responsibility could be enforced more successfully than the responsibility assumed by the doctor administering the vaccine. Therefore, the vaccine producers do not have the necessary motivation for increasing the safety of their vaccines as much as possible.

We can therefore conclude by saying that the State should assume the responsibility for side effects of both obligatory and optional vaccinations that are covered and recommended by the State, as soon as possible. Most parents do not see any difference between these two types of vaccinations and consider them as a state-guaranteed welfare, which is in the interest of their children as well as in the interest of the entire society. The responsibility of the State and the procedure for enforcing the responsibility should be defined by the law, either by a special regulation or by an amendment to an act, e.g. the Act on public health protection.

However, the problem encountered in practice is failing to properly inform the parents about the vaccination, to give them information not only about the benefits of the vaccination, but also about its risks and alternative solutions regardless of the fact, who bears responsibility for possible complications. It can be therefore recommended that standardized written informed consent forms should be created for all vaccines covered and recommended by the State. These informed consent forms should also contain information about risks and alternative solutions as well as information on how to watch for possible adverse effects of vaccination. The forms would be prepared for parents to go through before vaccination, and the parents should also have the opportunity to consult and ask questions about the vaccination.

Possibility for changing vaccines by doctors and parents

Currently, the State selects the vaccines that are administered to children according to the immunization schedule. Quite undoubtedly, the National Advisory Committee on Immunization and the representatives of the Ministry of Health influence these decisions, thus producing one strong and good-at-lobbying supplier of vaccines. Those doctors who want to recommend the parents a different vaccine, which they think would be more suitable, or who want to oblige the parents and administer a different vaccine outside the immunization schedule are "rebuked" by the National Advisory Committee on Immunization. The Committee would subject them to inspections and would punish the parents for wishing to choose a different vaccination without a contraindication by making them pay the full price for the vaccination.

We may ask what the reason behind such procedure is and who benefits from it? If the market offers more kinds of vaccines against a certain disease, and if all of them fulfil certain criteria and are properly registered, then there is no reason for the State to interfere with the doctor-patient relationship and restrict their possibilities of choice. Especially considering that it is the parents and the paediatrician who know best the medical and other needs of their child. On the contrary, if the final decision concerning the selection of a particular vaccine is made by the parents together with the paediatrician, it is much more likely that it will be the interest of the child that will be taken into consideration, and not the interest of a particular vaccine producer.

Doctors should have the possibility for changing one vaccine for another registered vaccine if this is in the interest of protection of the health of an individual child or if the parents wish so. A differ-

ent vaccine should be fully covered if it is changed for reasons of health protection, or covered up to the amount covered by State if it is changed upon the parents' request.

Vaccination campaigns: public health protection or just advertising?

David Zahumenský

Advertising[87] is everywhere we look. It is in the television, in magazines, on the Internet, in our e-mail, just everywhere. Promotional and marketing activities are an essential part of nearly every kind of entrepreneurship. We know that advertisements are powerful enough to make us spend our money and increase consumption, however we accept it as a part of life in a free society.

Nevertheless, there are some cases in which there is more at stake than just the money in our wallets, which is why certain kinds of advertisements are forbidden. Apart from restrictions upon tobacco and alcohol advertising, most countries agree on prohibition of advertisements for prescription drugs. There is one exception valid in all countries of the European Union, though. The exception concerns promotion of vaccines in compliance with an approved vaccination campaign.

The purpose of this article is to consider the reasons behind the current legal regulations concerning advertisements for prescription drugs, to point at deficiencies in the process of vaccination campaign approval in the Czech Republic, and to suggest such measures that might help improve the situation.

Regulations concerning advertisements for prescription drugs in European law

According to the report presented by the British House of Commons, in the US, major pharmaceutical companies spend of the order of 24% to 33% of sales on marketing, about twice as much as on research and development.[88] As far as the advertising is aimed at professionals, the emphasis is put on adequate provision of information and restriction on opportunities for corruption, as there exist strict rules for drug companies concerning health care workers sponsorship. On the contrary, as far as advertising aimed at lay persons is concerned, the promotion of prescription drugs is banned in the EU, whereas in the USA and New Zealand it is allowed.[89]

In the EU, the ban on direct-to-consumer advertising of prescription drugs for human use (hereinafter "direct-to-consumer advertising of prescription drugs") is given by the Directive 2001/83/EC of the European Parliament and of the Council,[90] which is based on the Directive 92/28/EEC. Ac-

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[87] According to the provision of § 1 para. 2 Act No. 40/1995 Coll., on restrictions on advertising, advertising is defined as *"an announcement, demonstration or other form of presentation made mainly in communication media, aiming at supporting entrepreneurship, especially supporting consumption or sale of merchandise, construction, rent or sale of real estate, or exercise of rights or obligations, supporting provision of services, promotion of a trademark, unless defined elsewhere otherwise.* "

[88] See House of Commons. "The Influence of the Pharmaceutical Industry" Fourth report of Session 2004-5. London 2005, p. 25. Available online at: http://www.publications.parliament.uk/pa/cm200405/cmselect/cmhealth/42/42.pdf. For more details see the article by Eva Kučerová in the present analysis.

[89] Cf. Geyer, R.: The Politics of EU Health Policy and the Case of Direct-to-consumer Advertising for Prescription Drugs', The British Journal of Politics and international Relations, Vol. 13, Issue 4, November 2011. Available online at: http://www.psa.ac.uk/2009/pps/Geyer.pdf. Quoted with author's consent.

[90] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use.

cording to Art. 88 para. 1 of the Directive 2001/83/EC, Member States shall prohibit the advertising to the general public of medicinal products which are available on medical prescription only.[91]

Why do we restrict public advertising of prescription drugs at all? First, we should consider the fact that prescription drugs are usually used as treatment for more serious diseases, are more toxic, and it is more difficult to understand their benefits and risks. That is also the reason why these drugs are not freely available but have to be sold only upon a medical prescription. Therefore, the purpose of the legislation restricting advertising is health protection.[92] The fact that advertising can have a negative impact on public health has also been confirmed by the Court of Justice of the European Union.[93] For these reasons the advertising of prescription drugs is allowed only if it is aimed at physicians and health care workers who are supposed to be able to consider the adequacy of the provided information,[94] and the advertising aimed at general public is banned.

Exception for approved vaccination campaigns

The Directive 92/28/EEC already provided for the exception to the ban on public advertising of prescription drugs concerning approved vaccination campaigns. This provision has been taken up by the Directive 2001/83/EC; article 88, paragraph 4 of the Directive, states that the prohibition of public advertising of prescription drugs shall not apply *"to vaccination campaigns carried out by the industry and approved by competent authorities of the Member States"*.

The purpose of this exception is not explained either in the Community law or in the Czech law, we can only conclude that the purpose should be the attempt to leave it up to the Member States to allow advertising promoting vaccination in case that it is necessary for public health protection – for example, if there exists a risk of an epidemic of an infectious disease. Such reasoning would be in compliance with Point (2) of the preamble of the Directive 2001/83/EC, which says that *"the essential aim of any rules governing the production, distribution and use of medicinal products must be to safeguard public health"*.

Now may be a good time to stop and think about it a little. The essential purpose of advertising is the promotion of sales of products and services, therefore it can hardly be considered as an objective source of information. Then, why don't the states prefer to keep the possibility for providing information on risks of some infectious diseases to themselves? Why do the states leave this space for vaccine producers, instead? We can hardly find other answer than that it is the consequence of the influence exercised by vaccine producers.

The simple fact that vaccine producers invest in advertising can lead us to conclude that direct-to-consumer drug advertising increases the consumption of the advertised drugs. However, this is also proved by conducted research studies. For example, a US market research firm, PERQ/CHI ana-

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[91] However, paragraph 4 of the Article states that the prohibition shall not apply to vaccination campaigns carried out by the industry and approved by the competent authorities of the Member States. This exception will be further discussed below.

[92] See Health Action International: Direct-to-Consumer Prescription Drug Advertising – The European Commission´s Proposal for Legislative Change. December 2001, p. 2. Available online at: http://www.haiweb.org/campaign/DTCA/BMintzes_en.pdf.

[93] See e.g. the decision in the case of Frede Damgaard, C-421/07. Decision delivered on 2nd April 2009. Published in a collection of decisions, 2009, I-02629.

[94] However, according to the Directive as well as the § 5b of the Act on restrictions on advertising, the advertising aimed at professionals must contain exact, up-to-date, verifiable and sufficiently complete data enabling the professional to form an opinion on the therapeutic value of the medicinal product.

lyzed the returns on investments in advertising in 1999 among 25 vaccine producers. On each dollar invested in direct-to-consumer advertising, the average return was $1.69 for TV ads alone; $2.51 for magazine advertising, and $2.11 for campaigns involving a mix of print and TV ads.[95]

In April 2008 the European Commission conducted research attempting to answer the question whether the pharmaceutical industry is a good provider of information for prescription medicines. The results of consultations are not surprising. Whereas 96% of pharmaceutical organizations and 72% of media representatives gave an affirmative answer, only 7% of health care organizations, 11% of regulators and none of the addressed patients' associations and insurance companies representatives said "Yes".[96] Advertising will always be advertising. Here we may ask the question whether the fact that the advertising was *"approved by the competent authorities of the Member States"* does not make the information contained in the adverts more trustworthy and whether this does not reinforce the impact of the vaccine advertising. Yet, the use of vaccines as well as other prescription drugs can be followed by many possible side effects, some of them may even turn fatal.

The European Parliament currently discusses an amendment to the directive 2001/83/EC, which originally extended the exception to the ban on direct-to-customer prescription drug advertising to *"public health campaigns in general and approved by the competent authorities of the Member States"*.[97] However, in the course of the legislation changes approval other amendments were approved, such as the proposal of the Committee of the Regions of the EU to narrow the exception, instead of extending it, only to campaigns *"with regard to preventive travel vaccines"*.[98]

However, so far this counterproposal, which would significantly restrict the possibilities of commercial promotion of vaccines in the EU, has not been accepted. The approved amendment to the Directive of October 2011 is based on a certain compromise. The current exception made for approved vaccination campaigns has been maintained but the provision of article 88 para. 4 of the Directive has been extended to contain the following text: *"such vaccination campaigns shall be approved by the competent authorities of the Member States only if it is ensured that objective, non-biased information is provided by the industry in the framework of the campaign regarding the efficacy, the adverse reactions and contra-indications of the vaccine"*.[99]

In my opinion, public health protection would be best improved by the absolute removal of the exception to the ban on vaccine advertising, nevertheless, the current amended proposal for the Directive represents at least an effort to set out certain rules of vaccination campaigns approval. It is mainly the lack of rules and an elaborate system for approving vaccination campaigns that leads to a situation, in which basically any advertisement for vaccines is approved in the Czech Republic

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[95] Quoted according to Health Action International: Direct-to-Consumer Prescription Drug Advertising – The European Commission´s Proposal for Legislative Change. December 2001, p. 3. Available online at: http://www.haiweb.org/campaign/DTCA/BMintzes_en.pdf.

[96] Geyer, R.: The Politics of EU Health Policy and the Case of Direct-to-consumer Advertising for Prescription Drugs', The British Journal of Politics and international Relations, Vol. 13, Issue 4, November 2011. Available online at: http://www.psa.ac.uk/2009/pps/Geyer.pdf. Quoted with author's consent.

[97] To all appearances, this is another effort of vaccine producers to gain more space, as they have repeatedly failed to achieve the removal of the ban on advertising of drugs in the EU.

[98] Opinion of the Committee of the Regions on the "Pharmaceutical package" (2010/C 79/10). Available online at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2010:079:0050:0057:EN:PDF.

[99] See the amended proposal available online at: http://ec.europa.eu/health/files/patients/ip_10-2011/dir_ip_2011_en.pdf.

without any review. Therefore, complementing the text of the exception would definitely do no harm.

Vaccination campaigns in the Czech Republic

Merely a simple formality. These are the words that a drug company might use for describing the system for approving vaccination campaigns in the Czech Republic. All they have to do is to submit a brief request, which will be granted within a couple of days.[100] There is no danger of the request being rejected, simply because the Ministry of Health never review anything. As the Ministry repeatedly states in its brief, one-page, opinions *"the subject of the approval is merely the adequacy of the vaccination campaign organization within a certain period of time; the contents of the vaccination campaign as such is not a subject of approval..."* In 2011 the League of Human Rights asked the Ministry of Health for its opinions on vaccination campaigns given in the past three years, and they are all just one like the other. What are the reasons behind the current state of things in the Czech Republic, in which the exception to the ban on direct-to-customer advertising of prescription drugs is interpreted in such way as to mean that any vaccine advertising is beneficial for general public?

The first reason is the insufficient implementation of the Directive 2001/83/ES in the Czech law. According to art. 288 of the Treaty on the Functioning of the European Union a directive shall be binding, as to the result to be achieved, upon each Member State to which it is addressed, but shall leave to the national authorities the choice of form and methods. In general, the European law works in such way that a directive defines the goals that are binding on member states, and the member states are obligated to implement (transpose) the directive in their legal order so as to ensure a proper application of the directive.[101]

As far as the implementation of the exception to the ban on direct-to-customer prescription drug advertising is concerned, the text of the directive has merely been implemented in the Act on restrictions on advertising. According to the provision of § 5a para. 2 letter b) of the Act, medicinal products for human use available only on medical prescription cannot be subject of direct-to-customer advertising, and according to para. 3 the ban does not apply to medicinal products used within the framework of a vaccination campaign approved by the Ministry of Health. As we can see, the text of the European directive has simply been copied, yet the Directive is merely meant to define boundaries for national lawmakers. However, the valid legislation does not contain any detailed definition of a vaccination campaign contents or any principles of its approval. I am therefore convinced that the Directive 2001/83/EC has not been properly implemented in the Czech legal order yet.

Another factor contributing to the current state is the fact that "vaccination campaigns" run by vaccine producers are reviewed behind closed doors at the Ministry of Health. There is no broader conception of vaccination promotion, and neither the professionals nor the general public are allowed to participate in the discussion concerning the vaccinations that should or should not be publicly promoted.

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[100] E.g. the request submitted by GlaxoSmitkKline, s.r.o. concerning promotion of vaccine Cervarix, which was delivered to the Ministry of Health on 7th December 2009 and granted on 16th December 2009. See the decision of the Ministry of Health of the Czech Republic, No. 58387/2009/OZV. In 2010 the same company submitted a request on 23rd November 2010, and the request was granted on 30th November 2010 – see the decision No. 67844/2010-3/OZV.

[101] Malíř, J., Štěrbová, M.: Způsob transpozice směrnic. Právní rozhledy 14/2004.

Lawyers of the League of Human Rights tried to change the situation and in November 2011 they challenged several acts of vaccination campaign approval taken in 2010 and 2011 in the Supreme Administrative Court for being so-called *measures of general scope*. They claimed that although the term "vaccination campaign" is not specifically defined in the Czech law, its substance corresponds with the definition of a measure of general scope according to § 171 and subs. of the Act No. 500/2004 Coll., Code of Procedure. If the Court confirmed the legal opinion that an approval of vaccination campaign is a measure of general scope, which means that it is an administrative procedure act with a specifically defined subject and a generally defined target audience,[102] then the validity of such approval would be conditioned by fulfilment of very strict criteria, especially those concerning the possible participation of public.

However, in its decision delivered on 14th December 2011, No. 3 Ao 7/2011 – 48 the Supreme Administrative Court denied the motion saying that approval of vaccination campaign is not a measure of general scope, since *"although it is issued upon the request of a company producing medicinal products for human use, it does not represent a decision on any rights or duties of the claimant or of other addressees of the respondent's public-administrative action. The approval of vaccination campaign is rather a realization of the respondent's competence to govern education towards support and protection of public health and to govern vaccination. In this case the respondent realizes this competence in the form of an opinion given in compliance with provisions of part four of the Act No. 500/2004 Coll., Code of Procedure. This opinion in itself does not interfere with rights and duties of consumers (i.e. potential addressees of the producer's offer), and does not imply any commitment, it is merely an expert corrective against massive advertising campaigns for certain kinds of medicinal products for human use, in particular for vaccines."*

The Supreme Administrative Court thus refused to state that criteria used for measures of general scope should also apply to the process of vaccination campaign approval and concluded that it is not even a decision, against which it would be possible to appeal. On the other hand, the Court also concluded that the opinion of the Ministry of Health should be *"an expert corrective against massive advertising campaigns for vaccines"*. By saying this, the Court indirectly asked the Ministry of Health to change the practice of automatically approving all vaccination campaigns.

According to Point (40) of the preamble of the Directive 2001/83/EC the provisions governing the information supplied to users should provide a high degree of consumer protection, in order that medicinal products may be used correctly on the basis of full and comprehensible information. From this we may conclude that the competent authority of the Member State should always carefully consider whether they will make an exception to the universal ban on advertising for a vaccine producer. The significance of such careful consideration lies in the fact that by allowing the advertising the authorities automatically make space for possible abuse. The fact that this is not just a speculation was proved in 2010, when GlaxoSmithKline, s.r.o., as a submitter of advertisement for vaccine Cervarix, was given fines of 200,000 CZK and 500,000 CZK by the State Institute for Drug Control because the advertising leaflets on the vaccine Cervarix contained misleading and untruthful information. The fine of 500,000 CZK is one of the highest fines the State Institute for Drug Control has imposed in the past ten years for breach of the Act on restrictions on advertising.[103]

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[102] For more details about the definition of a measure of general scope see the decision of the Constitutional Court delivered on 16th June 2010, File No. IV. ÚS 1639/2007., or the decision of the Plenum of the Constitutional Court delivered on 19th November 2008, File No. Pl. ÚS 14/07.

[103] Information taken from the reply sent by the State Institute for Drug Control following a request for information. Letter sent on 9th December 2011, File No. Sukls145618/2011. For more details see Eva Kučerová's article in the present analysis, in particular Table No. 10.

An example of approved vaccination campaign

MINISTERSTVO ZDRAVOTNICTVÍ
ČESKÉ REPUBLIKY

MZDRP00XDR6V

V Praze dne 16. prosince 2009
Č.j: 58387/2009/OVZ

Ministerstvo zdravotnictví jako správní úřad příslušný podle § 5a odst. 3 zákona č. 40/1995 Sb., o regulaci reklamy, ve znění pozdějších předpisů, vydává na základě žádosti společnosti **GlaxoSmithKline, s.r.o., se sídlem Na Pankráci 17/1685, 140 21 Praha 4,** o schválení vakcinační akce na očkovací látku proti infekci lidskými papilloma viry (HPV) s názvem **CERVARIX™** v období od 1.1.2010 do 31.12.2010 toto stanovisko:

Z odborného hlediska je vakcinační akce na očkovací látku CERVARIX™ vhodná.

Odůvodnění:
Dne 7.12.2009 byla Ministerstvu zdravotnictví (dále jen „ministerstvo") doručena žádost společnosti GlaxoSmithKline, s.r.o., se sídlem Na Pankráci 17/1685, 140 21 Praha 4, o schválení vakcinační akce na očkovací látku **CERVARIX™** v období od 1.1.2010 do 31.12.2010. Ministerstvo posoudilo tuto žádost s oporou v zákoně č. 40/1995 Sb., ve znění pozdějších předpisů, a v zákoně č. 258/2000 Sb., o ochraně veřejného zdraví a o změně některých souvisejících zákonů, ve znění pozdějších předpisů, pouze z hlediska, zda je realizace vakcinační akce z odborného hlediska vhodná. Konstatujeme, že vzhledem k tomu, že HPV infekce může ve svém důsledku vést až k vývoji cervikálního karcinomu, považujeme provedení očkování očkovací látkou CERVARIX™, za vhodné.
Předmětem tohoto schválení je pouze vhodnost realizace vakcinační akce z hlediska odborného; předmětem schválení není obsah vakcinační akce jako takový a schválení ministerstvem nenahrazuje souhlasy ani kontrolní činnost jiných správních úřadů.

Poučení:
Proti tomuto stanovisku není samostatný opravný prostředek přípustný.

MUDr. Michael Vít, Ph.D.
hlavní hygienik ČR a
náměstek ministryně

MINISTERSTVO ZDRAVOTNICTVÍ
poštovní přihrádka č. 81
Palackého náměstí č. 4
128 01 PRAHA 2
-27-

Palackého náměstí 4, 128 01 Praha 2
tel./fax: +420 224 971 111, e-mail: ovz@mzcr.cz, www.mzcr.cz

Examples of advertising leaflets on vaccination against cervical cancer published by vaccine producers, following a vaccination campaign of the Ministry of Health

Excursion: vaccination campaign in Germany and Austria[104]

Germany

According to the provision of § 10 para. 1 of the German Act on advertising of medicinal products (BGBl. I S. 3068, Heilmittelwerbegesetz) advertising of prescription drugs is admissible only if aimed at professionals. Vaccination campaigns aimed at public are organized in Germany but they promote merely vaccination against a certain disease, and not a particular vaccine. Realization of a particular vaccination campaign has to be always approved by the Ministry of Labour, Health and Social Affairs of the respective constituent state, especially on basis of recommendation by the Standing Committee on Vaccination at the Robert Koch Institute (STIKO) or on basis of the current epidemiological situation – e.g. as a reaction to increased incidence of a certain infectious disease in a particular area. The realization and scheduling of these events is under the charge of state or regional medical health care authorities (the authorities are part of the public health care system).

The basic legal regulation governing the control over public health is the Act on public health care services, whereas each constituent state has their own act. E.g. according to the provision of § 9 para. 1 of the Act valid in Baden-Württemberg (hereinafter BW)[105] or in North Rhine-Westphalia (SPV)[106] lower health care authorities contribute to prevention of and struggle against contagious diseases. At the same time these authorities strive to ensure the realization of necessary vaccinations (vaccinations recommended by the STIKO – the Standing Committee on Vaccination at the Robert Koch Institute, which yearly issues a list of recommended vaccinations – an immunization schedule). If necessary, the authorities can also run the vaccinations. Furthermore, the authorities keep records on and assess the number of vaccinated people.

Every year a campaign for vaccination against tick-borne encephalitis is organized. A considerable attention is given to this disease on a special website, www.zecken.de. Users can download a guidebook containing information on areas, where ticks occur, which diseases they transmit and how they transmit them, what the course of tick-borne encephalitis is, whether this disease may be followed by any permanent effects, what the symptoms of borreliosis are, which areas in Germany (and in Europe) have an increased occurrence of ticks, whether it is possible to get vaccination against tick-borne encephalitis, what the course of the vaccination is, how the vaccination is tolerated, what one should do in case of tick bite and how to remove a tick.[107]

Advertisements for particular vaccines are not allowed in Germany. E.g. if you look up the vaccine Cervarix, then, on the German website, this part is protected by password and available solely to professionals. On the contrary, on the Czech website[108], you can read very detailed information and you can even see a picture of the vaccine.

We can conclude that in Germany, vaccination campaigns (always well justified) never promote a particular product, a particular vaccine.

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[104] This part has been written with the help of lawyer Klára Snášelová.
[105] Act No. 663/1994 Coll., on public health care services, Gesetz über den öffentlichen Gesundheitsdienst.
[106] Act SGV. NRW. 2120, on public health care services, of 25th November 1997, Gesetz über den öffentlichen Gesundheitsdienst des Landes Nordrhein-Westfalen (ÖGDG NRW).
[107] See http://www.zecken.de/service/info-broschueren/.
[108] http://www.cervarix.cz/cervarixtm.html.

Austria

Drug advertising in Austria is governed by the Act No. 185/1983 Coll., (BGBl. Nr. 185/1983), on production and distribution of medicinal products (Act on medicinal products), in particular by part V., provisions of § 50 - 56a. According to the provision of § 51 para. 1 of the Act on medicinal products, direct-to-customer advertising of prescription drugs is banned. According to the provision of § 51 para. 2 of the Act on medicinal products, this ban does not apply to vaccination campaigns conducted or supported by the authorities (in the federal states or communities).

The Supreme Health Council (Oberste Sanitätsrat) yearly issued a recommended immunization schedule – a list of recommended vaccinations, including the recommended age of vaccination, and other recommendations concerning revaccination. Vaccination campaigns are therefore organized either on the basis of the recommendation by the Supreme Health Council (especially general vaccinations – e.g. against measles, tick-borne encephalitis) or on basis of the current epidemiological situation (e.g. vaccination against swine influenza).

The only vaccination campaign that was organized in 2011 (from 1st January to 31st July 2011) in entire Austria was the campaign for vaccination against tick-borne encephalitis. It was also supported by a pharmaceutical company – Baxter. This campaign is run yearly, the website, www.zecken.at, provides detailed information on the disease and the vaccination against it. However, even the website of the Baxter Company[109] does not publicize a particular vaccine – it only provides basic information about the currently launched campaign, including a notification that the vaccines are sold at a discount in pharmacies in the course of the campaign.

In the federal state of Salzburg campaigns for vaccinations against Hepatitis B, tick-borne encephalitis, Meningitis C and measles have been organized in the past years. In 2011 the only launched campaign was the campaign for vaccination against tick-borne encephalitis (FSME). It was run in spring 2011, independently of the national campaign, at all elementary schools in Salzburg. The vaccination attendance was voluntary.[110]

In Austria the exception to the ban on direct-to-customer advertising of prescription drugs is interpreted with restraint. As far as vaccination campaigns organized in federal states are concerned, these are usually well justified.

Conclusion and recommendations

On basis of the above-mentioned analysis I will take the liberty of suggesting the following recommendations for increasing the consumer protection in the Czech Republic and fulfilling the requirements of the European Union law:

1) **For campaigns concerning protection against infectious diseases objective information tools should be employed, such as will be based on scientific data provided by state authorities and professional medical societies. Information on possibilities of prevention of a particular disease should be preferred to information on particular vaccines. It should be taken into consideration that advertising is not a means of**

[109] See http://www.baxter.at/patienten_angehoerige/impfen-persoenliche_vorsorge/zeckenschutz-impfaktion.html.
[110] See http://www.salzburg.gv.at/themen/gs/gesundheit/landessanitaetsdirektion-2/abt9impfungen/impfaktionen.htm.

passing on objective information, but that the purpose of advertising is the promotion of sales of products and services.

2) **The Directive 2001/83/EC should be finally transposed so that the Czech legislation would contain specific criteria and procedural rules for approving vaccination campaigns.**

3) **The process of approval of vaccination campaign organization should take into consideration the request of the Supreme Administrative Court in order to fulfil the condition of *"an expert corrective against massive advertising campaigns for vaccines"*. The benefits of vaccination as well as its risks should be carefully considered.**

4) **The approval of vaccination campaign organization should be granted after careful consideration and only on condition that objective information on the vaccine effectiveness, side effects and contra-indications are provided.**

5) **Any tools employed in campaigns for protection against infectious diseases should be based on a long-term national conception and should take into consideration the development of the watched relevant indicators.**

Unlawful financial rewards for testing vaccines on children

Zuzana Candigliota

Prior to its introduction to the market, each medicinal product has to be properly registered. When submitting a request for registration, it is also necessary to present results of clinical trials, in lay-person's terms the results of testing on humans (the subjects of trials). This obviously concerns vaccines as well, since they fall into the category of medicinal products. However, vaccines often have to be tested on children, as a significant number of vaccines are intended for children, and testing the product on adults would not show the actual effects of the vaccine on a child's health. The purpose of a clinical trial is to find out or verify clinical, pharmacological or other effects of the product, to establish its side effects, and verify its safety or effectiveness.

There is nothing wrong with testing unregistered medicinal products and vaccines on children as long as it is done in compliance with the law, with an informed consent and in a transparent manner (privacy protection is a matter-of-course) and the interest of minors is a priority. However, the current practice leads to **violations of rights of minors, whose participation in a clinical trial should be motivated solely by the prospect of their welfare and not by the financial reward offered to their parents**. The State Institute for Drug Control refuses to deal with this unlawful practice. At the same time it is impossible for the public to **access information on the currently carried out clinical trials, on the trials approved by ethics committees and under which conditions they are approved. Yet, the trials are financed by sponsors of the study (e.g. vaccine producers), who can, therefore, be sure that their opinions will be kept from the public**.

General conditions concerning clinical trials

The basic principles of a clinical trial or human subject research in biology and medicine are defined by the Convention on Human Rights and Biomedicine. Among other things the Convention states that the risks must not be disproportionate to the potential benefits of the research and there must be no alternative of comparable effectiveness to research on humans, the research project has to be properly **assessed, including a review of its ethical acceptability** and approved, the persons undergoing research must be informed of their rights and they must expressly give their consent. According to the Convention, minors can participate in research on condition that research of comparable effectiveness cannot be carried out on adults capable of giving consent and that the results of the research have the potential to produce **real and direct benefit to the child's health**. If the research does not have the potential to produce results or direct benefit to the health of the child concerned, then research may be approved only exceptionally on condition that it entails **only minimal risk and minimal burden for the individual concerned**.

The "clinical trials of medicinal products for human use" are further defined in § 51 and subs. of the Act No. 378/2007 Coll., on medicinal products, which is based on EU regulations. According to these provisions a clinical trial can be launched and conducted only on condition that the ethics committee and the State Institute for Drug Control assess that the expected benefits justify the risks. Other conditions include that the participating person (hereinafter "subject of trial") is well informed about the testing as well as about their rights, that the person gives their informed consent; emphasis is also put on privacy protection and liability insurance.

Apart from the provisions of the Act on clinical trials of medicinal products there is also the implementing regulation No. 226/2008 Coll., on good clinical practice and further conditions for clinical trials of medicinal products.

Restrictions upon testing of medicinal products on children

According to § 52 para. 2 letter a) point 4 of the Act on medicinal products the physician who is in charge of the testing is obligated to ensure that the clinical trial **is not conducted on persons under 18 years of age**. However, this ban on clinical trials conducted on minors is instantly removed under certain conditions for clinical trials conducted on minors, which all have to be fulfilled at the same time. Among other conditions it is also necessary to:

- obtain an informed consent of legal representatives,
- inform the minor in a manner appropriate to their age and understanding,
- respect the minor's wish if they refuse to participate,
- ensure that the study has a direct benefit for more patients and has to be important for verification of data derived from clinical trials on adults or from other research methods, while the research should be relevant either to the disease the minor suffers from or its nature should be such as to make it necessary to conduct it solely on minors,
- have the report on clinical trial approved by an ethics committee competent to deal with issues concerning minors,
- **minimize pain, discomfort, fears and any other expectable risks** related to the given disease and the development of the subject of trial.

However, the most important condition for the research conducted on minors and for writing this article is that **it is possible to conduct clinical trials on minors only on condition that "no financial inducement save for compensation is offered."**

Ban on financial rewards for minors

As we have already mentioned, it is forbidden to offer any financial inducements, save for compensation, for participation in research. On the other hand, in case of adults capable of giving consent to participate in research, it is possible to offer them financial compensation as well as rewards. This stems from the fact that as far as adults are concerned, financial rewards or inducements are not explicitly banned. Another reason behind it is the fact that the law provides for the assessment of the amounts of rewards and compensations for persons participating in research, by ethics committees. It is therefore clear that in some cases rewards are admissible.

It is obvious that the law makes a sharp difference between **an inducement, financial amount or reward** on one side and **a compensation** on the other side. Although the law does not provide any detailed definition and the mere grammatical interpretation is not enough, the logical, systematic and teleological interpretation leads to a clear conclusion that **compensation is a reimbursement (for money spent, lost earnings or possible damage) and an inducement, financial amount or reward is a motivational financial amount (regardless of actual costs)**.

These terms are grounded in the Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials of medicinal products for human use and they were implemented in the Czech law basically unchanged. The exact wording in English goes: *"Clinical trial on minors may be undertaken only if no incentives or financial inducements are given except compensation."*

From the above mentioned we may conclude that **all subjects of trials can be given a so-called compensation but only adults enjoying legal capacity can be furthermore given rewards, inducements and financial amounts**. Such distinction is undoubtedly important, as **the legal representatives of minors should not be motivated to let children participate in a potentially**

dangerous research by money, but they should act solely in the best interest of the child. In case of vaccination, a mommy should consent to her child's participation in research only if she is persuaded, on the grounds of information provided by the physician in charge of the testing, that the vaccine would actually help her child and that the child's participation in research may help the society. She should never consent to it if her sole motive is the contribution to the family budget.

Compensation should, therefore, be interpreted as reimbursement of actual expenses or loss. If anyone interpreted compensation as reimbursement for time spent in and difficulties connected with the research, then, the awarded amount should be very low, otherwise it may be considered a reward. However, the concept of reward implies remuneration for a non-standard act, which is clear when we consider that rewards are also remunerations awarded to employees. If the non-standard participation was included in the compensation, then, this interpretation would cancel out the reasons for the legal distinction between the two terms.

The same legal opinion is shared by the authors of the textbook Medicínské právo (Medical Law), in which they say: *"Neither a minor nor their legal representative can be offered an inducement or financial amount except for compensation for possible* ***costs****."*[111] The implementing regulation provides for compensation for **expenses** as well.

More details on the ban

The legal regulations concerning the ban on rewards for research is in general based on an ethical concept, according to which no one should be motivated by a financial reward to run risks to one's health. The only benefit should be inner satisfaction and a good feeling that one participated in research in order to help the society or themselves. If a person was motivated to participate in research by a financial reward, then it would lead to violation of principles of justice, as financially disadvantaged people would bear a greater risk. On the other hand, it is not difficult to understand that the sponsors of research try to get enough participants in their study by motivating them financially.[112]

In case of minors, who are not capable of giving consent, it is up to their legal representatives to decide about the minors' participation in research. Financial rewards provoke questions of ethics, as they may influence the parents' decision. The possibility of a financial benefit may make the parents give consent to research, which they would otherwise refuse to give saying that it is not in the best interest of the child. Financial inducement may lead the parents to unconsciously exaggerate the benefits and underestimate the risks connected with the participation of their child in research. This is alarming especially if we consider that it is primarily up to the parents to decide on the child's participation in research; they can get financial benefit without being exposed to any risks. The possibility of financial reward can lead some parents to make a decision, which is in their own interest, while ignoring the risks to their child's health.[113]

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[111] Těšinová, J., Žďárek, R., Policar, R. Medicínské právo. 1. Vydání. Praha: C. H. Beck, 2011, p. 174.
[112] Davidson, A. J., O´Brien, M. Review article. Ethics and medical research in children. Pediatric Anesthesia, Blackwell Publishing Ltd. 2009/19, p. 1002.
[113] Wendler D., Rackoff J. E., Emanuel E. J. et al. The ethics of paying for children's participation in research. J Pediatr 2002; 141: p. 166.

Role of an ethics committee

Concerning clinical trials, the Act on medicinal products also provides for the work of so-called ethics committees. These are independent authorities formed mainly by health care professionals and they are established by health care services providers, in particular hospitals or the Ministry of Health. According to the law, the list of the ethics committee members must be available to public. Before a clinical trial is launched, following a request submitted by the sponsor the ethics committee gives an opinion on the clinical trial and on related issues. **The role of the ethics committee is to protect the rights, safety and health of persons who participate in research.** The costs associated with the opinion giving are covered by the sponsor of the clinical trial.

According to the law, when forming an opinion, an ethics committee must also consider:

- whether **the assessment of expected benefits and risks is acceptable** and whether the conclusions are justified,
- **the amount of a reward or compensation** awarded to examiners and subjects of the trial and other relevant aspects of all agreements concluded between the sponsor and the trial centre. The ethics committee must consider these compensations and rewards with regard to protection of rights, safety and health of the subjects of the trial.

The giving of opinion on clinical trial is further defined in the regulation No. 226/2008 Coll., on good clinical practice and further conditions for clinical trial of medicinal products. The regulation states that an ethics committee gives its opinion on the grounds of a written request and after considering documents presented by the examiner or sponsor of the study. The ethics committee is also presented with detailed information on compensations for expenses and rewards for subjects of the trial.

According to the regulation, when considering compensations and rewards, the ethics committee must always consider:

- whether the compensation to the subject of the trial in case of death or damage to health occurred due to the subject's participation in the clinical trial is provided for in an insurance contract,
- **whether the compensation does not exceed the expense met by the subject of the trial** or by the examiner in connection with their participation in the clinical trial and whether the reward received by the examiner is known beforehand and is definitely fixed and whether the sponsor presented a written statement on the amount of the reward together with the request,
- whether the amount of reward corresponds with the nature of the clinical trial, especially with regard to those research acts that do not bring any direct benefits to the subject of the trial.

On the grounds of the above-mentioned regulations concerning the work of ethics committees it is obvious that the committee should consider the amount of offered rewards and compensations with regard to the protection of rights, safety and health of the subjects. However, it remains to be answered whether in practice, the work of the committees is not motivated more by the interest of the research sponsors, who pay for the work of the committee, and whose interest is to get enough participants in research conducted on minors. That is why the sponsors wish to motivate the parents to let their children participate in research.

However, considering its nature, a compensation can be awarded only subsequently, after the subject presents documents proving expenses associated with the clinical trial (usually travel expenses and compensation for lost earnings). It can also be possible to provide an advance on compensation and subsequently, after documents proving actual expenses are presented, the advance is

accounted for. Nevertheless, it certainly is not in compliance with the protection of rights, safety and health of minors to provide "compensations", which are not based on documents proving actual expenses, and which, in reality, are rewards. This is circumvention of the law and the ban on provision of rewards for research conducted on minors.

Availability of information on ethics committees and clinical trials

The Act on medicinal products defines what information about ethics committees and clinical trials have to be provided, in other words disclosed. However, from the point of view of the patient or subject of trial, this scope of information is absolutely insufficient.

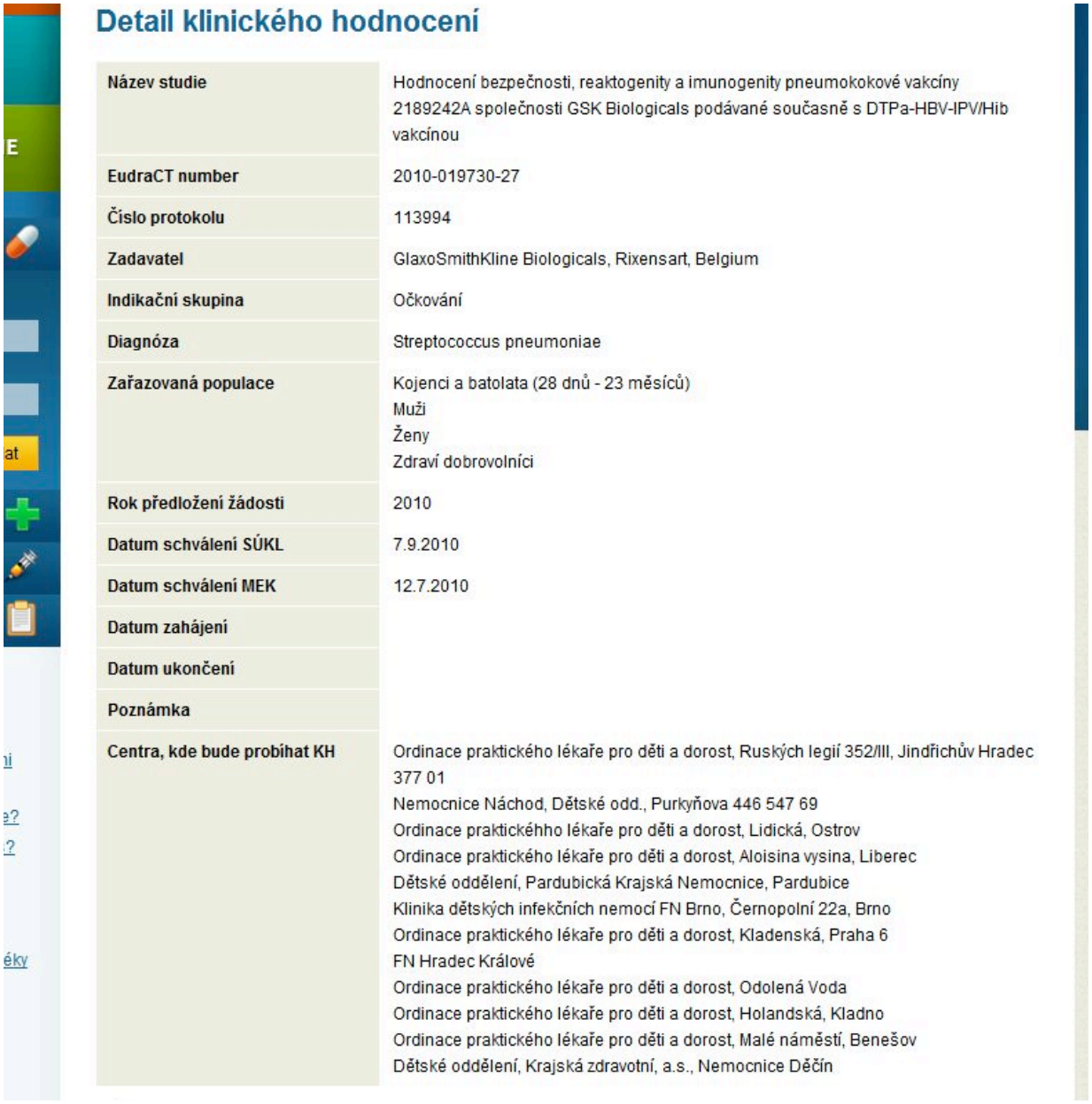
The entity that established the committee (a care provider or the Ministry) is responsible for disclosing the rules for meetings and working procedures of an ethics committee, the list of the committee members, as well as compensations for expenses associated with the giving of opinion.

The State Institute for Drug Control discloses a list of ethical committees in the Czech Republic, giving away the contact address of the ethics committee, the specialization of its members, the date of establishment and, possibly, dissolution, and whether it is an ethics committee on multicentre clinical trials and the opinions the ethics committee gave on proposed clinical trials.

The Institute also discloses *"information on clinical trials, which can be launched in the Czech Republic, with the exception of bioequivalence studies and studies, in the course of which a medicinal product is administered to a human being for the first time."*

In practice, it means that the disclosed information regards the name of the study, protocol number, sponsor, indications (e.g. vaccination), diagnosis, population in clinical trial (e.g. infants and toddlers), year of receiving the request, date of approval by the Institute, date of approval by ethics committee on multicentre clinical trials, date of initiation and ending of the clinical trial, and sites, at which clinical trials are to be conducted. **However, the name of the responsible doctor is not mentioned, this can be only inferred if it is an independently working doctor, who is the only one residing at the given address.** Otherwise, it is not possible to infer from the disclosed information who is in charge of the given project. It is impossible to get further information about the clinical trial from the Institute, as it will be discussed further on. **Thus, neither the subject of the trial nor their parents have the possibility for verifying any information on the study.**

Taken from the website of the State Institute for Drug Control



Detail klinického hodnocení

Název studie	Hodnocení bezpečnosti, reaktogenity a imunogenity pneumokokové vakcíny 2189242A společnosti GSK Biologicals podávané současně s DTPa-HBV-IPV/Hib vakcínou
EudraCT number	2010-019730-27
Číslo protokolu	113994
Zadavatel	GlaxoSmithKline Biologicals, Rixensart, Belgium
Indikační skupina	Očkování
Diagnóza	Streptococcus pneumoniae
Zařazovaná populace	Kojenci a batolata (28 dnů - 23 měsíců) Muži Ženy Zdraví dobrovolníci
Rok předložení žádosti	2010
Datum schválení SÚKL	7.9.2010
Datum schválení MEK	12.7.2010
Datum zahájení	
Datum ukončení	
Poznámka	
Centra, kde bude probíhat KH	Ordinace praktického lékaře pro děti a dorost, Ruských legií 352/III, Jindřichův Hradec 377 01 Nemocnice Náchod, Dětské odd., Purkyňova 446 547 69 Ordinace praktickéhho lékaře pro děti a dorost, Lidická, Ostrov Ordinace praktického lékaře pro děti a dorost, Aloisina vysina, Liberec Dětské oddělení, Pardubická Krajská Nemocnice, Pardubice Klinika dětských infekčních nemocí FN Brno, Černopolní 22a, Brno Ordinace praktického lékaře pro děti a dorost, Kladenská, Praha 6 FN Hradec Králové Ordinace praktického lékaře pro děti a dorost, Odolená Voda Ordinace praktického lékaře pro děti a dorost, Holandská, Kladno Ordinace praktického lékaře pro děti a dorost, Malé náměstí, Benešov Dětské oddělení, Krajská zdravotní, a.s., Nemocnice Děčín

Case study – clinical study of Novartis on meningococcus B

In 2009 a study was conducted in the Czech Republic, entitled "A Phase III, partially blinded, randomized, multicentric, controlled study to evaluate the immunogenicity, safety and consistency of lots of recombinant meningococcal B vaccine by Novartis administered with usual vaccination to healthy infants". The study documentation states that the coordinator and investigator in the Czech Republic is Doctor Roman Prymula.

In the written informed consent to clinical trial there is information about the meningococcal disease, reasons for conducting the study, the course of the study, the possible risks and benefits associated with participation in the study, measures to be taken in case of harm, reward and costs and expenses associated with the participation in the study, protection of personal data and other information.

The form of the informed consent describes risks associated with participation in the study only slightly, it gives priority to less relevant data (results of trials using only one component of the tested vaccine, and results of trials on adults, not infants), the relevant information on serious side effects were only given by the end and were typed in small font size (see the cuttings – only in Czech).

Furthermore, it remains to be answered why the ethics committee approved the simultaneous administration of the new vaccine and Infanrix Hexa (a hexa vaccine) and Prevenar, allowing vaccination of children against eight diseases at the same time, instead of separate administration of the tested vaccine. As it will be explained later, these reasons will be kept secret, since it is impossible to lawfully obtain the documentation of the ethics committee. The alternative possibility of separate vaccine administration is never mentioned in the informed consent form and it remains to be answered whether such procedure is consistent with the principle of risk minimization, as it is required by the Convention on Biomedicine.

Informed consent cutting – reward

Formulář informovaného souhlasu
(Informace + Prohlášení o souhlasu)
Protokol: V72P13

Novartis Vaccines & Diagnostics

Jaká je odměna za účast ve studii, vzniknou mi nějaké výdaje a náklady?

Za lékařskou péči poskytnutou v rámci studie nebudete muset platit, ani za potřebné laboratorní testy a prohlídky. Účast ve studii Vás nebude nic stát, ale neobdržíte ani žádnou finanční odměnu. Budou Vám uhrazeny cestovní náklady spojené s návštěvami v rámci studie paušální částkou 900,- Kč za 1 návštěvu. Celkem Vám bude uhrazeno 4500,- Kč splatných po návštěvě 3 a 5 (celková částka rozdělená na dvě části 2700,- Kč a 1800,- Kč). Podmínkou je účast dítěte na všech návštěvách ve studii. Pokud bude účast dítěte předčasně ukončena nebo bude dítě vyřazeno ze studie před jejím dokončením, nebo pokud studie skončí dříve, obdržíte dílčí úhradu podle počtu návštěv, kterých se Vaše dítě zúčastnilo.

Informed consent cutting – risks 1

Jaká jsou předpokládaná rizika spojená s účastí ve studii?

Na Novém Zélandu byly podány více než 3 miliony dávek vakcíny obsahující OMV (součást hodnocené vakcíny rMenB + OMV). Jako reakce na tuto vakcínu se objevily: místní bolestivost, zarudnutí, otok, podráždění a horečka.

K dnešnímu dni se vyhodnocováním vakcíny rMenB zabývá deset klinických studií. V těchto studiích je vakcína rMenB podávána buď samostatně, nebo v kombinaci se složkou OMV, která je stejná nebo podobná složce používané v této studii. Dokončeny již byly čtyři studie u dospělých subjektů, jedna studie u dospívajících a dvě studie s velmi malými dětmi. V současné době probíhají tři studie: jedna u velmi malých dětí, jedna u dospívajících a jedna u dospělých subjektů.

Ukončené studie s dospělými ukazují, že jsou obě vakcíny obecně bezpečné a dobře snášené. Nejběžnější reakcí na vakcíny rMenB a rMenB + OMV byla mírná až střední bolest v místě vpichu. Vyskytly se také méně běžné reakce jako zarudnutí, zatvrdnutí nebo podlitina v místě vpichu injekce. Většina osob, které obdržely tyto vakcíny, pocítila mírné až střední celkové svalové bolesti. Ti, kdo obdrželi vakcínu rMenB, měli menší svalové bolesti než ti, kdo obdrželi vakcínu rMenB + OMV. Ve studii s dospělými nebyla hlášena žádná závažná nežádoucí příhoda (SAE - např. hospitalizace, smrt, život ohrožující onemocnění) ve vztahu se zkoušenou vakcínou.

Údaje přicházející z dokončených studií u velmi malých dětí prokázaly podobné reakce včetně mírného a krátkodobého zvýšení tělesné teploty po aplikaci první injekce. Mezi další reakce, které lze očekávat a o jejichž sledování Vás chceme požádat, patří: změna stravovacích návyků u Vašeho dítěte, ospalost, podrážděnost, neobvyklý pláč, zvracení, průjem a vyrážka. Tyto reakce jsou obvykle mírné a krátkodobé (zpravidla byly pozorovány během 7 dní po podání vakcíny).

Z předběžných údajů přicházejících z této studie vyplývá, že horečka se vyskytuje častěji u dětí, které dostaly vakcínu rMenB+OMV současně s běžnými vakcínami, než u dětí, které dostaly běžné vakcíny nebo běžné vakcíny v kombinaci s vakcínou proti meningokoku typu C po první vakcinaci. Tato horečka souvisí se zvýšeným výskytem dalších reakcí, které již byly popsány.

Vedle výše uvedených příhod mohou existovat reakce na vakcíny, které dosud nejsou známy. Jako u všech vakcín existuje možnost alergické reakce na vakcínu, a proto budeme Vaše dítě sledovat po dobu 30 minut po každém očkování. Zkoušející lékaři znají specifické postupy pro řešení těchto nepříliš pravděpodobných příhod.

Při odběru krevních vzorků může být v místě odběru pociťována určitá bolest a rovněž je možný vznik podlitiny po provedení odběru krve.

Doplňující informace

Vakcína rMenB se složkou OMV nebo bez ní se právě zkouší ve třech studiích s malými dětmi (dvě studie již byly dokončeny a jedna studie ještě probíhá). K dnešnímu dni byly ohlášeny tři vážné nežádoucí účinky (SAE), u nichž se předpokládá, že souvisí s vakcínou.

K prvnímu závažnému účinku, reaktivní artritidě v pravém koleni (zánět kloubu), došlo asi měsíc po aplikaci čtvrté dávky vakcíny rMenB bez OMV, která byla podána s jinou běžnou vakcínou. Podle lékaře studie, jestliže k tomuto účinku došlo do jednoho měsíce po aplikaci dvou vakcín, souvislost se zkoumanou vakcínou nelze zcela vyloučit.

Druhým účinkem byla horečka vyžadující hospitalizaci (39,5°C), která se bez jakýchkoli specifických příznaků vyskytla u dvouměsíčního dítěte ve stejný den, kdy byla podána vakcína rMenB+OMV spolu s dalšími běžnými vakcínami. Následující ráno horečka odezněla a dítě bylo zase v pořádku. Tento vážný nežádoucí účinek lze předvídat, protože v předcházející studii u malých dětí bylo zjištěno, že horečka se objevuje hlavně po první dávce vakcíny rMenB+OMV u dvouměsíčních dětí.

Třetí nežádoucí účinek se vyskytl v den vakcinace, kdy byla podána vakcína rMenB+OMV spolu s dalšími běžnými vakcínami. Během večera dítě dostalo horečku (38,6°C), pořád plakalo a nedalo se utišit. Při pláči dítě občas ztuhlo a jeho obličej ztratil výraz. Byla přivolána sanitka. Po příjezdu se stav dítěte vrátil k normálu. Dítě nebylo hospitalizováno a jeho stav zůstal normální. U dítěte zřejmě nastalo dočasné přerušení dechu, ke kterému nejpravděpodobněji mohlo dojít v souvislosti s horečkou, bolestí a pláčem po očkování.

Informed consent cutting – risks 2

Jedna složka stávající vakcíny rMenB, byla také hodnocena v dřívější studii se 36 dospělými dobrovolníky, kteří byli očkováni vakcínou s touto složkou nebo bez ní. Vakcíny byly všeobecně bezpečné a dobře snášené. V této studii byl hlášen jeden závažný nežádoucí účinek. Byla to mírná mozková mrtvice postihující čití u obézního muže středního věku, k níž došlo 48 hodin po podání vakcíny. Jak zkoušející lékař, tak lékaři, kteří tohoto muže ošetřovali, považují vztah se zkoušenou vakcínou za nepravděpodobný. Avšak záchvat nemohl být považován za rozhodně nesouvisející, protože nebyl zjištěn žádný jiný rizikový faktor než obezita. Tato příhoda byla tedy klasifikována jako pravděpodobně související se zkoušenou vakcínou.

Jaké výhody jsou spojeny s účastí ve studii?

Nemůžeme Vám zaručit, že bude mít Vaše dítě přímý prospěch z účasti v této studii.
Podle toho, do jaké skupiny bude zařazeno, si bude Vaše dítě moci po podání vakcíny rMenB+OMV a/nebo běžného očkování vytvořit protilátky proti nemocem jako jsou meningokokové infekce skupiny B, tetanus, záškrt, černý kašel, dětská obrna, hemofilové infekce typu B, hepatitida B a pneumokokové infekce.

Můžeme předpokládat, že vakcína rMenB + OMV bude stimulovat imunitní systém Vašeho dítěte, aby si vytvořil protilátky proti bakterii typu B (MenB), i když k tomuto předpokladu zatím nemáme žádné důkazy. Informace získané v této studii nám pomohou dozvědět se více o této vakcíně a pomohou proto v budoucnosti chránit lidi proti onemocnění působenému meningokokem typu B.

Po skončení studie Vám sdělíme výsledky krevních zkoušek (budou-li provedeny). Dozvíte se, zda Vaše dítě reagovalo na podanou vakcínu MenB a/nebo běžné vakcíny. Podle objemu vzorku bude možné, že neobdržíte výsledky týkající se všech onemocnění, proti kterým bylo Vaše dítě očkováno. Avšak pokud zjistíme, že u Vašeho dítěte nedošlo k žádné reakci na běžné očkování, nabídneme mu podání další dávky příslušné očkovací látky.

Opatření pro případ újmy

Novartis Vaccines odpovídá za poškození zdraví v důsledku újmy způsobené zkoušeným lékem a má příslušné odpovídající pojištění pro krytí takovéto újmy související se studií.

Pokud dojde k mimořádné události, kdy Vaše dítě utrpí nějakou tělesnou újmu nebo onemocnění v důsledku jeho účasti ve studii, bude mu okamžitě poskytnuta nebo zprostředkována lékařská péče. Budou uhrazeny veškeré náklady související s touto lékařskou péčí.

Aby mohla být uplatněna pojistná smlouva, musíte dodržovat veškeré pokyny a rady lékaře týkající se účasti Vašeho dítěte ve studii a neučinit nic, co by napomohlo této újmě nebo ji způsobilo. Novartis Vaccines Vám neposkytne žádné odškodnění za újmu způsobenou Vašemu dítěti, pokud bude tato újma důsledkem nějakého postupu, který nebyl proveden v souladu s protokolem studie. Vaše zákonné právo na odškodnění za újmu způsobenou Vašemu dítěti nelze uplatnit, pokud Vám bude možné prokázat, že jste něco zanedbali.

Informace o pojišťovně:
HDI Hannover Versicherung AG, organizační složka, Jugoslávská 620/29, 120 00 Praha 2
tel.: 220 190 210
Pojistná smlouva číslo: 2.000.100 (76-001102-01010)

Pokud by se v průběhu studie objevily nějaké komplikace nebo byste chtěli získat nějaké další informace, obraťte se na lékaře svého dítěte, nebo na koordinujícího zkoušejícího lékaře v ČR:

Jméno koordinujícího zkoušejícího lékaře v ČR: **Prof. MUDr. Roman Prymula, CSc., PhD.**
Číslo telefonu: 973 253 101 **Číslo faxu: 495 513 018** **Bezplatná linka: 800 173 333**

In the excerpt from the informed consent concerning reward for participation in research it is clearly given that **parents will not obtain any financial reward**. On the other hand, it is also given that the parents will get a compensation of 4,500 CZK for alleged expenses without having the obligation to prove the actual expenses. The mother of the child participating in the study, who gave us these documents, said that she did not have to bear any actual expenses associated with the participation in the study – she was home with the child, so there were no lost earnings, and she walked to the doctor's office, so there were no travel expenses either. Moreover, the tested vaccine was administered together with regular vaccination, so there was no much extra time wasted. Yet, she obtained the given amount in two instalments from the company BIOVOMED, association for support of research and development. The mother also said that she participated in the study mainly because of the offered financial amount.

It is obvious that for the majority of parents the offered amount of 4,500 CZK is not insignificant, thus they can be motivated to have their children participate in research rather by this sum then by the best interest of the child. Apparently, the law is being circumvented to the disadvantage of minors. According to our information, this was not a singular case.

State Institute for Drug Control verifies

In June 2011, on the grounds of these findings, the League of Human Rights submitted a request for information to the State Institute for Drug Control (hereinafter "Institute"), putting, among others, these questions:

- request for a **list of all approved clinical trials of vaccines conducted on children under 18 since 2005, including all related background materials, which the Institute has at disposal** and which are not available on the Institute website, including all background documents and reports provided by the sponsor and all background documents and reports provided by the ethics committee, etc.,
- whether, with regard to the clinical trials mentioned in the previous point, **the Institute supervises the provision of compensations to the child's family and whether it checks whether the compensations are not, in reality, a pretext for providing rewards for participation in clinical trial**,
- whether, with regard to the clinical trials mentioned in the first point, it is possible to administer the tested vaccine together with other vaccine, taking into consideration **the principle of risk minimization**,
- whether, with regard to the clinical trials mentioned in the first point, the Institute ensures that **families are properly informed** about the nature, significance, impact and risks of the clinical trial.

In reaction, the Institute rejected the first point of the request for information, on the grounds that the information is not resulting from use of public means, and was obtained from a person who is legally not obligated to provide the information and who did not give consent to the provision of the information. According to the Institute, the background materials for the clinical trial are an exclusive property of the study sponsor. [114]

To further questions the Institute replied:

[114] Decision of the State Institute for Drug Control delivered on 12th July, File No. Sukls119597/2011.

- According to the Act on medicinal products and the provisions of § 53 para. 7 letter j) and § 53 para. 8 of the Act **the ethics committee have the exclusive competence to consider the amount and the payment of rewards or compensations to examiners and subjects of trial.**
- The ratio of risks to benefits of a medicinal product is evaluated in every clinical trial, i.e. the risk to patients/healthy volunteers compared to the possible benefit with regard to the administered medicinal product. The possibility for administering more vaccines at the same time is also a matter for consideration and it is discussed with external collaborators of the Institute (experts in a given field); we consider these within the framework of every clinical trial as well as with regard to the compulsory immunization schedule. We consider administration of several vaccines at the same time as well as administration of polyvalent vaccines.
- The Institute as well as the ethics committees consider the text of the Information for patients/Informed consents. In compliance with the provision of § 57 para. 3 of the Act on medicinal products, the Institute also supervises the fulfilment of legal requirements and principles of good clinical practice. The actual presence of the Institute inspectors when information is provided to individual patients is not acceptable with regard to the protection of the subjects of trial.

That is why in July 2011 the League of Human Rights put forward **a motion to the Institute concerning verification of a possibly unlawful act committed in clinical trials**. We did it on the grounds of the fact that, according to the law, the Institute:

- allows clinical trials of medicinal products,
- decides about trials termination or suspension,
- hears administrative offences concerning medicinal products for human use, and
- implements measures in case of violation of duties imposed by the Act on medicinal products.

However, the Institute is competent to suspend or prohibit the course of a clinical trial if the conditions in the relevant documents are not met or if the Institute obtained new information, which is significant for the safety of the subjects of the trial or for scientific justification of the clinical trial. Yet, given that clinical trials on minors are financially motivated, which is in contradiction with the law, the safety of minors is undoubtedly affected, as the purpose of the ban is to protect minors.

In the above-mentioned motion the League of Human Rights required that **health care facilities, which participated in clinical trials in the past years, should be randomly inspected for providing rewards for clinical trials on minors, although it is in contradiction with the law.**

In the motion the League of Human Rights also pointed out that in its previous reply, the Institute mentioned that it is up to the ethics committees to consider the amount of rewards, however, in the case of minors, the provision of rewards is legally banned, which means that the ethics committee had nothing to approve. Yet, in practice, rewards, and not compensations, which would be acceptable in case of minors, are provided.

In August 2011 Zdeňka Mertová, the employee of the Institute, responded to our motion by sending us an email, asking us to provide further documents to check and identify the study and the health care facility, in which unlawful acts were committed according to the League of Human Rights. At the same time she pointed out that ***"provision of compensations is in compliance with the Act No. 378/2007 Coll., on medicinal products and on changes of some related acts (act on medicinal products), as amended by later regulations; and the consent to it is given by an appropriate ethics committee by means of an informed consent, according to the provision of §53 para. 8 of the Act on medicinal products in compliance with the provision of §52 para. 6 letter d). "***

In the course of the following months the League of Human Rights send further documents related to health care facilities, in which rewards were supposedly offered to parents for participation in a clinical trial, to the Institute via email and telephone. At the same time the League of Human Rights repeatedly pointed out that the Novartis Company expressly states in the informed consent that the offered amount is not a reward, although in fact, it is a reward, as the family had no expense associated with travelling, and even if there were some travel expenses, they would never reach such a large amount, not even if the family took a taxi to get to the doctor's office for vaccination. **The League of Human Rights pointed out that it is an unambiguous case of circumvention of the law and motivation of parents by a financial benefit.**

In November Zdeňka Mertová informed the League lawyer via email that *"investigation is still in progress; the obtained facts are consistent with legal requirements and information obtained from informed consents."* The Institute promised to keep the League informed after the case is closed. However, this did not happen, and after being repeatedly asked, in January 2012 Ms Mertová replied again that the investigation is still in progress, that the cases will be closed by the end of January 2012, that the Institute is preparing a report and that the League will be informed after it is finished. Moreover, the League was again informed that *"the facts obtained in the course of inspections are in compliance with legal requirements and information obtained from informed consents and that no new facts have been revealed."* Up to now, the League has not obtained any further notice from the Institute.

Conclusion and recommendations

On the grounds of the above-mentioned legal regulations and of the case study I dare suggest some recommendations in the interest of protection of minors' rights, safety and health:

More transparent work of ethics committees

All background documents provided for ethics committees, so that they can give an opinion on clinical trials, and their reports should be available to public (and especially to subjects of trials), either upon request or directly on the websites of care providers associated with a given ethics committee. Only a necessary scope of information protected by the trade secret, which, at the same time, is not significant with regard to health of the subjects of trial, could be kept secret.

The current state allows the ethical committees to decide freely, to approve large amounts of rewards for research on minors and insufficiently consider the minimization of risks, and all this without letting it be known who in particular is responsible for the approvals.

However, to make the work of ethics committees more transparent, since it is currently concealed, it would be necessary to change the legal regulations.

Work of the State Institute for Drug Control

The State Institute for Drug Control should perform its legally defined role and solve cases of provision of unlawful motivational rewards for parents, which are labelled as "compensations" for the purpose of circumvention of the law, which are not based on actual expenses or lost earnings on the part of the family, and which are provided solely to persuade the parents into letting their child participate in a clinical trial. The Institute should also investigate whether the principle of risk minimization is respected instead of merely referring to a non-transparent ethics committee and its approval.

In order to work out solutions the Institute should make use of its competence to implement measures in case of violation of duties imposed by the Act on medicinal products, and it should also make use of the possibility for bringing administrative proceedings for an administrative offence, or even the possibility for terminating or suspending a clinical trial. Above all, the Institute should make use of its competences when allowing clinical trials of medicinal products.

Advertising and marketing of pharmaceutical companies

Eva Kučerová

Is society wasting the resources it devotes to advertising? Or does advertising serve a valuable purpose? Assessing the social value of advertising is difficult. (Mankiw, 2009)

Marketing and advertising as a part of business policy

Marketing is one of the concepts in a business policy. It incorporates an entire *process of research into market, and products or services sale*, aiming at achieving *maximum economic impact* by *systematically creating demand* for the offered product.[115] An important part of it is **advertising**. It is a paid form of impersonal mass communication aiming at informing consumers and influencing their behaviour. According to one of the definitions advertising is *"persuasive process, which uses communication media for seeking users of goods, services or ideas"*. The Act No. 40/1995 Coll., on restrictions on advertising and on changes and amendments to the Act No. 468/1991 Coll., on radio and television broadcasting, as amended by later regulations (hereinafter "Act on restrictions on advertising" or "ARA") explicitly defined that advertising includes all *"announcements, demonstrations and other presentations spread mainly by means of communication media, aimed at supporting business activities, especially supporting consumption or sale of goods …"*[116].

Advertising can also describe *"every address given while undertaking activities associated with business, trade, crafts or free enterprise, aimed at supporting sale of goods or provision of services"*[117]. According to the law advertising cannot be deceptive, hidden, subliminal or in contradiction with good manners. It must not support any behaviour that could be harmful to health or that could present a threat to safety of persons, property or environment. An advertisement is defined as **deceptive** if, in any way, it misleads or may mislead persons, at whom it is aimed, and if, due to its misleading nature, it probably affects their economic behaviour. When *considering* a possibly *deceptive advertisement*, it is necessary to take into account all its components, especially the contained information on the goods or services, namely the kind, design, composition, manner and time of manufacturing, or provision, purpose, quantity, geographical and commercial origin, expected results of use or results of testing, etc. (Tichý, 2006) According to the provision of § 45 para. 3 of the Act No. 513/1991 Coll., Commercial Code (hereinafter "Commercial Code") a piece of information can be considered **deceptive** *"even if it is truthful in itself, but when it is used in certain context and circumstances, it can be misleading"*[118].

Another important term describes **unfair business practices**, which can be defined as any *"actions, omissions and other forms of communication including advertising, which significantly corrupt the economic behaviour of the consumer by impairing their ability to take an informed decision, and which make the consumer take a decision they would not otherwise take"*[119]. The provision of § 4 para. 1 of the Act No. 634/1992 Coll., on consumer protection (hereinafter "Act on consumer protection")

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[115] http://www.dane-brno.cz/slovnik-ekonomickych-pojmu/detail/marketing.
[116] Act No. 40/1995 Coll., on restrictions on advertising and on changes and amendments to the Act No. 468/1991 Coll., on radio and television broadcasting, as amended by later regulations.
[117] Tichý, L., Arnold, R., Svoboda, P., Zemánek, J., Král, R. Evropské právo. 3. vydání, Praha: C. H. Beck, 2006, p. 614.
[118] Act No. 513/1991 Coll., Commercial Code.
[119] Tichý, L., Arnold, R., Svoboda, P., Zemánek, J., Král, R. Evropské právo. 3. vydání, Praha: C.H.Beck, 2006, p. 615.

describes a business practice as **unfair** *"if the conduct of the entrepreneur towards consumers is in contradiction with the requirements of professional care and is likely to significantly affect the consumers' decisions by making them take a decision they would not otherwise take"*[120].

Pharmaceutical marketing and advertising

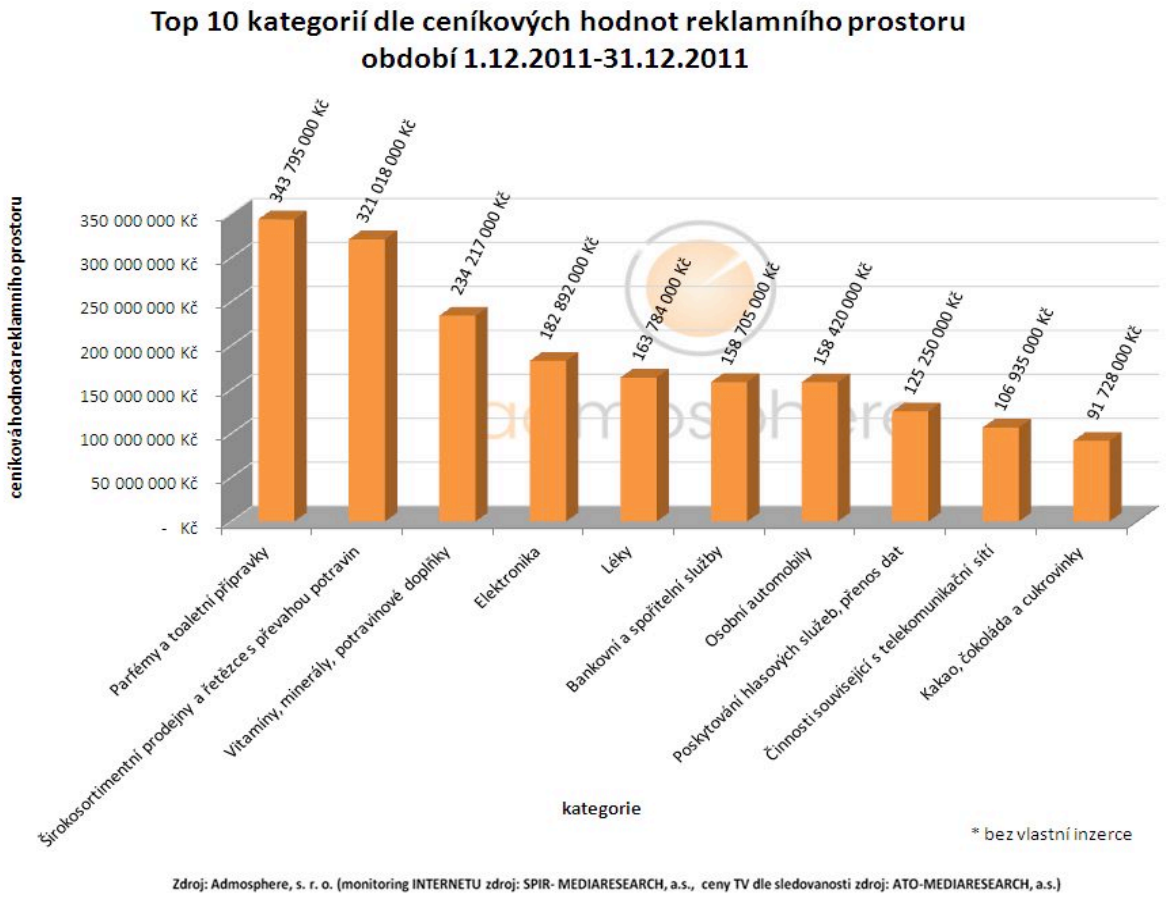
As we have already mentioned, **marketing** systematically creates demand for products on offer. Therefore, **the pharmaceutical marketing** systematically creates demand for medicinal products on offer.[121] However, **the advertising of pharmaceutical companies** is rather specific. Promotion and advertising of medicinal products serve an important role for the success and profitability of pharmaceutical companies, as well as for their future development; nevertheless, it must be done in an ethical and legal manner, considering that the health care is an area of exceptionally significant ethical dimension. **Medicinal products**, as well as tobacco products, alcoholic beverages or firearms and ammunition, are classified as ***so-called sensitive commodities***. The legal framework is formed, among others, by the **Act on restrictions on advertising**. The Act on restrictions on advertising makes a clear difference between the advertising aimed at professionals and advertising aimed at laypersons; it also specifically defines what both types of advertising may, must or must not contain.

Analysis of marketing and advertising expenses on the part of pharmaceutical companies

The amount of advertising varies substantially across products. Firms that sell highly differentiated consumer goods, such as over-the-counter drugs, typically spend between 10 and 20 percent of revenue for advertising. Firms that sell industrial products, such as drill presses and communication satellites, typically spend very little on advertising. And firms that sell homogenous products, such as wheat, peanuts or crude oil, spend nothing at all. (Mankiw, 2009)

As far as pharmaceutical companies are concerned, their products, whether food complements or prescription drugs, have been among ten greatest sponsors on a long-term basis.

[120] Act No. 634/1992 Coll., on consumer protection.
[121] http://www.zdn.cz/clanek/postgradualni-medicina/farmakoetika-eticke-a-pravni-aspekty-farmaceutickeho-marketingu--447558.



Zdroj: Admosphere, s. r. o. (monitoring INTERNETU zdroj: SPIR- MEDIARESEARCH, a.s., ceny TV dle sledovanosti zdroj: ATO-MEDIARESEARCH, a.s.)

According to the press release of Admosphere, a Czech medicinal products producer, the amount of financial resources invested in advertising significantly increased in 2011. The greatest investments were made by GlaxoSmithKline, Bayer and Novartis. So far, the analysis concerned the first half of 2011 and within this period, pharmaceutical companies increased their investments in advertising by 18,75% in comparison with the first half of 2010.

Table No. 1: Comparison of gross investments in advertising of Top Ten Sponsors – pharmaceutical companies between 1st January and 30thJune 2010 and 2011 (note: the Admosphere Company assesses advertising expense on the grounds of prices given in price lists)

Amounts given in thousands CZK.

Sponsor	Gross investment in advertising 1st January – 30th June 2011	Gross investment in advertising 1st January – 30th June 2010	Increase in %
GlaxoSmithKline	132 134 000	86 755 000	52%
Bayer	123 411 000	75 654 000	63%
Novartis	110 740 000	59 418 000	86%
Boehringer Ingelheim	97 280 000	54 556 000	78%
Zentiva	93 388 000	62 624 000	49%
Johnson&Johnson	88 815 000	54 788 000	62%
Medicom International	62 049 000	36 926 000	68%
Reckitt Benckiser (Czech Republic)	39 244 000	103 780 000	-62%
Janssen-Cilag	38 570 000	23 855 000	62%
Berlin-Chemie/A.Menarini Czech Republic	32 641 000	43 904 000	-26%

Source: Admosphere, s.r.o.

With the exception of Reckitt Benckiser (Czech Republic) and Berlin-Chemie/A.Menarini Czech Republic, which have reduced their advertising budgets, the remaining sponsors ranked Top Ten have decided to at least double their investments in advertising in the following year. The biggest increase in investments was on the part of Novartis, which spend 86 % more money on advertising than they did in the first half of the previous year. Novartis together with GlaxoSmithKline and Bayer placed first, second and third in the table. Research indicates that the campaigns conducted by pharmaceutical companies are mostly based on communication through television. (Admosphere, 2012)

Other means of medicinal products promotion

In most Western countries, direct-to-consumer drug advertising is banned, nevertheless, there are methods big pharmaceutical companies employ to influence public opinion and capture market for their products. They persuade doctors to prescribe their medicinal products, and they offer doctors free packages of medicinal products. They try to persuade the users of medicinal products of the necessity to use them, they sponsor patients' groups and campaigns warning against certain diseases. (Federation of consumers groups Consumers International, 2006)

Another means of "advertising" used by pharmaceutical companies is the so-called "congress tourism" for physicians. In 2011 pharmaceutical companies took doctors to more than two hundred congresses. The database of these congresses is a project of the Association of Innovative Pharmaceutical Industry (AIFP), which brings together thirty pharmaceutical companies in the Czech Republic. The database contains a list of world congresses, which Czech physicians can attend thanks to the sponsorship of AIFP member companies (www.lekarskekongresy.cz). The congress destina-

tions include cities in the Czech Republic as well as Paris, Versailles, New York, Las Vegas or Dubai, Honolulu and Cape Town.

Pharmaceutical companies use various means in order to persuade doctors that their medicinal product is the best, and there are billions of dollars at stake.

Table No. 2 compares financial means, which pharmaceutical companies invested in research and development of new drugs, with selling expenses in 2011 and 2010. The comparisons of research and development expenses in the following tables were based on consolidated financial statements of mother companies, as we assume that research is most likely centralized in multinational companies, and therefore the data will have greater informational value.

Table No. 2: Multinational companies specializing in production of medicinal products: Sales, Selling, General & Administrative Expense, Research and Development Expense – comparison

Amounts given in thousands USD.

Pharmaceutical company	Sales 2011	Selling, General & Administrative Expense (including advertising and marketing) 2011	Research and Development Expense 2011	Sales 2010	Selling, General & Administrative Expense (including advertising and marketing) 2010	Research and Development Expense 2010
Pfizer	67 425 000	19 468 000	9 112 000	67 809 000	19 614 000	9 413 000
Novartis	59 375 000	21 165 000	9 583 000	51 561 000	17 711 000	9 070 000
Merck & Co	48 047 000	13 733 000	8 467 000	45 987 000	13 245 000	10 991 000
GlaxoSmithKline	42 562 086	13 716 470	6 230 379	44 452 098	20 436 504	6 978 127
Abbott Laboratories	38 851 000	12 756 000	4 802 000	35 166 721	10 376 324	4 037 624
Sanofi-Aventis	45 510 365	11 489 880	6 245 375	42 976 348	10 521 726	5 904 133
Eli Lilly Co	24 286 500	7 879 900	5 020 800	23 076 000	7 053 400	4 884 200

Source: the data for the analysis were taken from financial statements on www.forbes.com and from annual reports of the individual companies.

The data were taken from financial statements published by Forbes (www.forbes.com) and verified in annual reports of the individual companies. The item **Selling, General & Administrative Expense – SG&A** is the sum of all direct and indirect selling expenses and all general and administrative expenses of a company. It is therefore merely referential information, as, apart from advertising, it also includes other expenses associated with sale support.[122] (www.investopedia.com)

[122] *Direct expenses are expenses that can be directly linked to particular actions (products or services) – for example, advertising expenses. Indirect expenses are expenses which cannot be directly linked to a particular ac-*

It is impossible to get the amount associated with advertising expenses only from the information obligatorily published by the companies. On the other hand, even if it was possible to get the information, it would probably be distorted, as the sum would not include expenses associated with other forms of promotion, which are common in the industry, and which would be hidden behind expenses associated with organization of congresses and conduction of studies, which are used by pharmaceutical companies for motivating physicians to prescribe particular drugs.

Table No. 3: Multinational companies specializing in production of medicinal products: Sales, Selling, General & Administrative Expense, Research and Development Expense – comparison and % of sales in 2011

Amounts given in thousands USD.

2011

Pharmaceutical company	Sales 2011	Selling, General & Administrative Expense 2011	% of total profits in 2011	Research and Development Expense 2011	% of total profits in 2011
Pfizer	67 425 000	19 468 000	29%	9 112 000	14%
Novartis	59 375 000	21 165 000	36%	9 583 000	16%
Merck & Co	48 047 000	13 733 000	29%	8 467 000	18%
GlaxoSmithKline	42 562 086	13 716 470	32%	6 230 379	15%
Abbott Laboratories	38 851 000	12 756 000	33%	4 802 000	12%
Sanofi-Aventis	45 510 365	11 489 880	25%	6 245 375	14%
Eli Lilly Co	24 286 500	7 879 900	32%	5 020 800	21%

Source: the data for the analysis were taken from financial statements on www.forbes.com and from annual reports of the individual companies.

Table No. 4: Multinational companies specializing in production of medicinal products: Sales, Selling, General & Administrative Expense, Research and Development Expense – comparison and % of sales in 2010

Amounts given in thousands USD.

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tion (products, services), but which are proportionally allocated to all units (actions – products or sales) sold during a certain period, such as telephone or postal charges. General and administrative expenses include salaries of non-sales personnel, rent, heat and lights.

2010

Pharmaceutical company	Sales 2010	Selling, General & Administrative Expense 2010	% of total profits in 2010	Research and Development Expense 2010	% of total profits in 2010
Pfizer	67 809 000	19 614 000	29%	9 413 000	14%
Novartis	51 561 000	17 711 000	34%	9 070 000	18%
Merck & Co	45 987 000	13 245 000	29%	10 991 000	24%
GlaxoSmithKline	44 452 098	20 436 504	46%	6 978 127	16%
Abbott Laboratories	35 166 721	10 376 324	30%	4 037 624	11%
Sanofi-Aventis	42 976 348	10 521 726	24%	5 904 133	14%
Eli Lilly Co	23 076 000	7 053 400	31%	4 884 200	21%

Source: the data for the analysis were taken from financial statements on www.forbes.com and from annual reports of the individual companies.

As the data in Tables No. 3 and 4 suggest, pharmaceutical companies spend 10 to 20 % of total annual sales on research and development. In our sample it is 5 to 10 billion dollars. Tables No. 5 and 6 feature pharmaceutical companies ranking from those with highest sales to those with lowest sales. The data in the Tables show that the amount of financial means invested in research and development increases as the company sales increase as well. However, the increase in not directly proportional. While the sales increased three times, the investments in research and development merely increased twice. The Tables also contain the item "Profit after tax"; these amounts are comparable to the amounts of investments into research and development.

Table No. 5: Multinational companies specializing in production of medicinal products: Sales, Research and Development Expense – comparison and % of sales in 2011

Amounts given in thousands USD.

Pharmaceutical company	Sales 2011	Research and Development Expense	% of sales	Profit after tax	% of sales
Pfizer	67 425 000	9 112 000	14%	10 051 000	15%
Novartis	59 375 000	9 583 000	16%	9 245 000	16%
Merck & Co	48 047 000	8 467 000	18%	6 272 000	13%
Sanofi-Aventis	45 510 365	6 245 375	14%	7 390 339	16%
GlaxoSmithKline	42 562 086	6 230 379	15%	8 176 110	19%
Abbott Laboratories	38 851 000	4 802 000	12%	4 729 000	12%
Eli Lilly Co	24 286 500	5 020 800	21%	4 347 700	18%

Source: the data for the analysis were taken from financial statements on www.forbes.com and from annual reports of the individual companies.

Table No. 6: Multinational companies specializing in production of medicinal products: Sales, Research and Development Expense – comparison and % of sales in 2010

Amounts given in thousands USD.

Pharmaceutical company	Sales 2010	Research and Development Expense	% of sales	Profit after tax	% of sales
Pfizer	67 809 000	9 413 000	14%	8 289 000	12%
Novartis	51 561 000	9 070 000	18%	9 969 000	19%
Merck & Co	45 987 000	10 991 000	24%	861 000	2%
GlaxoSmithKline	44 452 098	6 978 127	16%	7 674 970	17%
Sanofi-Aventis	42 976 348	5 904 133	14%	2 558 281	6%
Abbott Laboratories	35 166 721	4 037 624	11%	4 626 172	13%
Eli Lilly Co	23 076 000	4 884 200	21%	5 069 500	22%

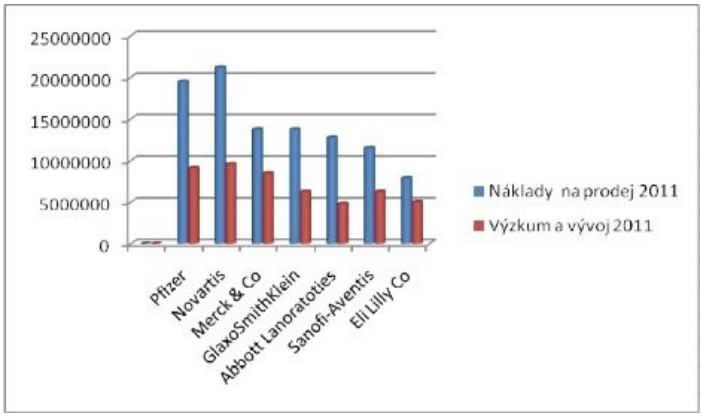
Source: the data for the analysis were taken from financial statements on www.forbes.com and from annual reports of the individual companies.

If we compare the items "Selling, General & Administrative Expense" and "Research and development Expense" in 2010 and in 2011 (see Tables No. 7 and 8), we will see that the Selling Expense represent twice the amount of Research and Development Expense.

Table No. 7: Multinational companies specializing in production of medicinal products: comparison of Selling, General & Administrative Expense and Research and Development Expense in 2011

Amounts given in thousands USD.

Pharmaceutical company	Selling, General & Administrative Expense 2011	Research and development 2011
Pfizer	19 468 000	9 112 000
Novartis	21 165 000	9 583 000
Merck & Co	13 733 000	8 467 000
GlaxoSmithKline	13 716 470	6 230 379
Abbott Laboratories	12 756 000	4 802 000
Sanofi-Aventis	11 489 880	6 245 375
Eli Lilly Co	7 879 900	5 020 800

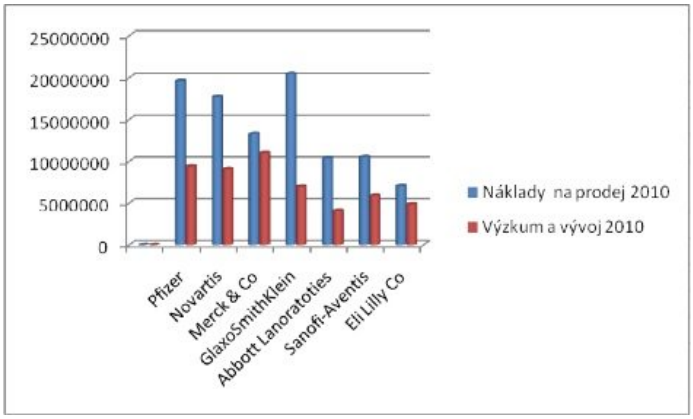


Source: the data for the analysis were taken from financial statements on www.forbes.com and from annual reports of the individual companies.

Table No. 8: Multinational companies specializing in production of medicinal products: comparison of Selling, General & Administrative Expense and Research and Development Expense in 2010

Amounts given in thousands USD.

Pharmaceutical company	Selling, General & Administrative Expense 2010	Research and development 2010
Pfizer	19 614 000	9 413 000
Novartis	17 711 000	9 070 000
Merck & Co	13 245 000	10 991 000
GlaxoSmithKline	20 436 504	6 978 127
Abbott Laboratories	10 376 324	4 037 624
Sanofi-Aventis	10 521 726	5 904 133
Eli Lilly Co	7 053 400	4 884 200



Source: the data for the analysis were taken from financial statements on www.forbes.com and from annual reports of the individual companies.

Analysis of administrative proceedings conducted by the State Institute for Drug Control from 2005 onwards

In 2005 to 2011 the State Institute for Drug Control (hereinafter "Institute") received 798 reports concerning possible violations of the Act No. 40/1995 Coll., on restrictions on advertising (hereinafter "ARA"). In this period, 70 administrative proceedings were initiated. 63 fines were imposed; in 7 cases the proceedings were suspended according to the provision of §66 para. 2 of the Act. 500/2004 Coll., Code of Administrative Procedure. In 17 cases fines were imposed on advertisement creators, 53 fines were imposed on sponsors and advertisement distributors.

The total amount of fines imposed in 2005 to 2011 was 9,745,000 CZK. The amount of fines imposed on sponsoring companies was 8,675,000 CZK, the amount of fines imposed on advertisement creators was 870,000 CZK and the amount of fines imposed on advertisement distributors was 200,000 CZK.

Table No. 9: The highest overall fines imposed on one entity in 2005 to 2011

Amounts given in thousands CZK.

Sponsor	Sales 2010	Fines in total	% of sales
GlaxoSmithKline	3 954 663	1 500	0,04%
Zentiva	1 359 118	1 003	0,07%
ACTAVIS CZ	173 129	750	0,43%
Boehringer Ingelheim	1 059 898	660	0,06%
Walmark	2 224 570	475	0,02%

Source: the data for the analysis were taken from www.justice.cz/ and from the report of the State Institute for Drug Control.

The highest amount of fines was paid by GlaxoSmithKline; they were imposed five fines amounting to 1,500,000 CZK in total. This represents 0.04% of the company annual sales (the fines were given for advertisements featuring "the motive of fear", "exaggerating the qualities of the medicinal product", comparative advertising, "making references to recommendations of fake experts and scientists", and for "providing information, which was not consistent with the review of information on medicinal product").

The second place belongs to Zentiva; they paid 1,003,000 CZK in total, which represents 0.07% of the company annual sales (the fines were given for "offering gifts or other forms of benefits of substantial value", "advertising medicinal products available only on prescription", "advertisement lacking obligatory requisites, which would enable professionals to form their own opinion" and for advertisements "containing information, which was not consistent with the review of information on medicinal product").

ACTAVIS.CZ ranked third with a fine of 750,000 CZK, which represented 0.43% of the company annual sales (the fine was given for an expert seminar held in Egypt, which was an advertising event for medicinal products, without being officially defined as such, and which offered "benefits of substantial value").

The fourth place belongs to Boehringer Ingelheim, which paid 660,000 CZK on fines in 2005 to 2011. This represents 0.06% of the company annual sales (the fine was given for providing "information, which was not consistent with the review of information on medicinal product", and for advertisement, which did not support "sensible use of medicinal product").

Walmark, ranked five, paid 475,000 CZK, which represented 0.02% of the company annual sales (the fine was given for providing "information, which was not consistent with the review of information on medicinal product", and for offering "gifts or other forms of benefits of substantial value").

In total, 70 administrative proceedings were conducted against 51 different entities. In 19 cases, the violations of law were committed repeatedly. The following Table contains the individual fines

paid by those companies, which were imposed the highest fines in the given period. That is why we have selected these companies in our sample.

Table No. 10: Detailed review of fines imposed by the State Institute for Drug Control on selected companies in 2005 to 2011

Amounts given in thousands CZK.

Name of pharmaceutical company	Administrative proceedings initiated	decision – legal effect	Medicinal product	Fine	Violated provision of the Act on restrictions on advertising (ARA)
GlaxoSmithKline	7th May 2008	4th November 2008	Twinrix	300	§2 para. 3 and §5a para. 5 letter a)
GlaxoSmithKline	4th September 2011	9th July 2010	Panadol Baby	350	§5 para. 5, §5a para. 7 letter b), §5 para. 7 letter f)
GlaxoSmithKline	19th November 2009	9th July 2010	Cervarix	200	§5 para. 4, §5a para. 7 letter b), §5a para. 7 letter i)
GlaxoSmithKline	19th November 2009	11th May 2010	Cervarix	500	§5 para. 4, §5a para.7 letter b), §2 para.1 letter c)
GlaxoSmithKline	3rd May 2010	16th March 2011	Priorix-Tetra	150	§5 para. 4 of AoAR
Fines imposed on GlaxoSmithKline in total				**1 500**	
Zentiva	4th December 2007	28th February 2008	Lindaxa	120	§5a para. 2 letter a)
Zentiva	19th March 2008	24th July 2008	Cinie	183	§5b para. 2 letter a) and b)
Zentiva	9th October 2008	12th December 2009	Citalec, Esprital	550	§ 5b para. 4 letter a)
Zentiva	1st June 2009	19th September 2009	MUCOSIN	150	§5 para. 4
Fines imposed on Zentiva in total				**1 003**	
ACTAVIS CZ	6th March 2009	28th February 2011	Terbinafin Actavis	750	§2 para.1 letter d), §5 para. 4 letter a)
Fines imposed on ACTAVIS.CZ in total				**750**	
Boehringer Ingelheim	12th July 2005	16th September 2005	Menofem	25	§2b and §5a para. 4

Boehringer Ingelheim	19th October 2005	9th June 2006	Mucosolvan, Silomat	165	§5 para. 4
Boehringer Ingelheim	3rd July 2006	18th August 2006	Antistax	70	§5 para. 5, §5a para. 5 letter d)
Boehringer Ingelheim	18th September 2009	8th March 2010	MENOFEM	400	§5 para. 4
Fines imposed on Boehringer Ingelheim in total				**660**	
WALMARK	22nd May 2009	19th May 2011	Emoxen gel	350	§5b para. 4 letter a) and §5 para. 4
WALMARK	9th June 2010	9th February 2010	Emoxen gel	125	§5 para. 4
Fines imposed on WALMARK in total				**475**	

Source: the data for the analysis were taken from the report of the State Institute for Drug Control.

The highest fine with regard to the company annual sales was imposed on ACTAVIS.CZ; the fine represented 0.43% of the company annual sales. The other fines represented less than 0.1% of the companies' annual sales. Assuming that a pharmaceutical company yearly invests 10% to 20% of the company annual sales in advertising, then the **increase** in the **expense** of mere 0.5% (taking into account the lowest value we have received) is **insignificant**.

According to the provision of § 8a para. 5 to 8 of the Act on restrictions on advertising, the fines imposed for serious administrative torts can be up to 5,000,000 CZK. If we use the lowest annual sales in our sample for comparison, we will see that the highest possible fine would represent at the most 3% of company annual sales (5,000,000 CZK/173,129,000 CZK *100 = 2.89%).

The draft amendments to the Act[123] already take into account this situation and give the amount of 15,000,000 CZK as the highest possible fine for serious torts. If we compare it to the lowest annual sales of the listed companies, we will see that it represents approximately 9% of the annual sales (15,000,000 CZK/173,129,000 CZK *100 = 8.66%), however, if we compare it to the highest annual sales of the listed companies, we will get some 0.40% of the company annual sales (15,000,000 CZK/3,954,663,000 CZK *100 = 0.38%).

Conclusion

In the world today advertising is, in most cases, a greater and greater illusion. With regard to social responsibility and consumer protection, as the consumer is usually unable to obtain unbiased information about the promoted product, this area cannot be left without effective control. Especially if so-called sensitive commodities are concerned. With regard to the companies' annual sales, the so far imposed fines do not represent any serious financial threat to pharmaceutical companies. And as the practice shows, the fines certainly do not prevent the pharmaceutical companies from repeatedly committing administrative torts.

The purpose of legal regulations is to provide protection against socially undesirable phenomena. However, it is necessary to make the law "enforceable" in practice. The European Union legislation explicitly requires that the **sanctions** should be **effective, adequate and discouraging**. According

[123] http://eklep.vlada.cz.

to the causal report on the draft amendment to the Act on restrictions on advertising the amounts of sanctions *"defined in many **present** provisions of the law have barely any effect in some cases, and therefore it is desirable to increase them; the practice has shown that some pharmaceutical companies, which have high annual sales, find it **worth risking** being imposed a fine and commit unlawful acts, since even the highest possibly imposed fines do not represent any substantial financial loss for them... The draft amendment to the Act also specifically defines the possibly acceptable criteria for imposing fines, especially with regard to sales associated with a particular medicinal product, the amount and nature of benefits gained by committing unlawful acts and possible repeatedly committed violations of the law; these criteria should lead to an adequate differentiation between sanctions for revealed unlawful acts concerning advertising of medicinal products for human use."*[124] Nevertheless, I think that the proposed fines are still not sufficient. It would be more adequate and at the same time more effective not to restrict the amount of **fines** by a fixed amount but to associate it with the **percentage of the company sales**, and with regard to not only the promoted medicinal product. In case the law is violated repeatedly, the sales percentage would be multiplied by a coefficient, which would increase depending on the number of violations of the law. However, the mere increase in fines will probably not solve the problem. It would be more effective to change the system as such, or to adopt **a procedure for approving advertisements by a committee of medical experts before they are released in the media**, which would at least partly prevent fraudulent misinterpretations. If examinations upon entering the system are more strict, then it will not be necessary to impose such heavy sanctions, as those proposed above are. However, if there are no examinations and we only rely on the "moral" responsibility of the entities, then the increase in sanctions is adequate. It is necessary to choose either the one or the other way.

One of the alternative proposals features a restriction on advertising expenses associated with promotion of products covered partly or fully by public money, restricting the expenses to a percentage (3-4%) of the company sales, and arguing that in such case the society has the right to have the competitive expenses of pharmaceutical companies restricted. It surely is an interesting idea, yet there arise certain difficulties. For example, who would conduct the examination of such regulation? An auditor? Yes, an auditor might do so. However, auditors are not a State authority, and therefore they cannot impose sanctions. The revenue office? That would be possible in theory. Then, the percentage would have to be obtained from the previous accounting period in order to make the measure practically applicable. Or some other State authority? Besides, accounting, as much as it seems to be an exact discipline, is actually very creative. In other words, it is fairly easy to circumvent such regulation. One of the possible consequences may be the drop in prices for advertising and the increase in other services, which can be provided by advertising and marketing agencies, such as marketing survey, various sponsor gifts, etc. Anyway, if certain expenses are to be restricted by a percentage of company sales, then it would be good to adopt the measure properly and also restrict other items that are covered by public money. For example, pharmaceutical companies' dividends (see Appendix No. 2). These are private profits actually generated from obligatory health insurance payments or taxes (depending on the particular health care system). The remunerations paid to the management are quite substantial as well (see Appendix No. 3). Does the society have the right to control these? Another important aspect is the economic and political power of pharmaceutical lobby. Do such laws have any chance of being drafted?

More strict legal regulations concerning advertising are necessary, as some products may be presented as having very beneficial effects on health. As Roman Kobiela says in his book: *"This kind of advertising is highly effective and also highly dangerous, considering the possible fraudulent misinter-*

[124]http://webcache.googleusercontent.com/search?q=cache:Zs4CMu73nBsJ:www.komora.cz/download.aspx%3Fdontparse%3Dtrue%26FileID%3D7165+sankce+%C3%BA%C4%8Dinn%C3%A9,+p%C5%99im%C4%9B%C5%99en%C3%A9+a+odrazuj%C3%ADc%C3%AD+reklama&cd=4&hl=cs&ct=clnk&gl=cz

pretation. For middle-aged people and especially for retired people health is a priority. The effects of such adverts are enhanced, if the products are presented by celebrities."[125] Especially since the consumer-patient, influenced by advertising, has to rely on the advice and recommendations of professionals concerning the effectiveness of the product, from which they can choose – and these professionals, physicians and pharmacists, are also influenced by various marketing strategies.

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[125] Kobiela, R. Reklama. 200 tipů, které musíte znát. Brno: Computer Press, 2009, p. 92.

Appendix No. 1:

List of provisions, which were violated, leading the State Institute for Drug Control to initiate administrative proceedings, and the frequency of violations of each provision.

Provision of the ARA, which was violated	**wording**	**frequency of occurrence**
§5	*"any information contained in the advertisement for a medicinal product for human use must be consistent with the review of information on the medicinal product"*	22
§5b para. 2 letter a) and b)	advertisements aimed at professionals *"must contain a) exact, up-to-date, verifiable and sufficiently complete information enabling the professionals to form their opinion on the therapeutic value of the medicinal product for human use. Information taken from expert publications or papers must be precisely quoted and the source must be quoted, too, b) basic information consistent with the approved review of information on the medicinal product, including the date of approval or the date of last revision..."*.	17
§5b para. 2 letter d)	advertisement must not contain *"information on the mode of payments made from public health insurance money"*	10
provision of §5b para. 2 letter c)	advertisement must not contain *"information on the mode of dispensing of medicinal product for human use according to the licence"*	9
§5 para. 5	*"advertising of a medicinal product for human use must promote a sensible use of it by presenting the medicinal product in an unbiased manner and without exaggerating its benefits"*	7
§5a para. 2 letter d)	advertising aimed at general public must *"contain explicit, well readable, if printed, invitation to carefully read the patient information leaflet"*	7
§5b para. 4	*"as far as advertising of medicinal products for human use aimed at professionals is concerned, it is forbidden to offer, promise or give the professionals any gifts or other benefits, unless the gifts or benefits are of insubstantial value or related to their professional activities"*	6
§5a para. 5 letter a)	advertisement aimed at general public must *"explicitly state that the promoted product is a medicinal product for human use"*	5
§5a para. 5 letter c)	advertisement must contain *"information necessary for correct use of medicinal product for human use"*	4
§5a para. 7 letter i)	advertisement must not *"lead a person to incorrectly establish their own diagnosis by giving a detailed description of the course of the disease in a particular case"*,	4
§2 para. 1 letter d)	it is forbidden to publish *"an advertisement, which would be difficult to be identified as such, especially because it is not defined as advertisement"*	3
§2 para. 3	advertisement aimed at general public must not *"indicate that the effects of a medicinal product for human use are guaranteed, are not associated with possible adverse effects or are better than or equal to the effects of a different treatment or a different medicinal product for human use"*	3

§ 2 para. 1 letter c)	it is forbidden to publish *"an advertisement, which would be an unfair business practice according to a special legal regulation"*	2
§2 para. 2	*"Comparative advertising is permissible under conditions defined in the present Act and in a special legal regulation."*	2
§5b para. 3	*"In the course of every visit made for the purpose of advertising of a medicinal product for human use a sales representatives must give the professional the review of information on the medicinal product for human use, which is the subject of advertising, as well as the information on the mode of payment for the medicinal products for human use. A sales representative has the duty to present without unnecessary delay to the respective licence holders any information on significant facts, which they come across while performing their work activities, and which is related to the use of the advertised medicinal product, and especially any information on any adverse effects reported to the sales representative by professionals the sales representative visited."*	2
§5b para. 7	*"Samples of medicinal products for human use may be provided only exceptionally to persons authorized to prescribe these, and in a limited number for a maximum of twelve months, and every sample must correspond to the smallest package of the medicinal product for human use available in market and must be labelled as "Sample not for sale" or "Free sample". It is forbidden to provide narcotics or psychotropic drugs. Samples of medicinal products for human use may be provided only upon a written request made by a person authorized to prescribe these; the written request must be signed and must contain the date of submission."*	2
§5a para. 2 letter a)	*"Advertisement aimed at general public must not promote medicinal products for human use, which are only available on prescription."*	1
§5a para. 7 letter f)	*"Advertising aimed at general public must not recommend a medicinal product for human use, making a reference to a recommendation by scientists, health professionals or persons, who are neither scientists or professionals, but who could support the use of the medicinal products thanks to their real or assumed social position,"*	1
§5a para. 7 letter j)	*"Advertising aimed at general public must not point at the possibility of recovery in an inappropriate, exaggerated or misleading manner,"*	1
§5a para. 7 letter k)	*"Advertising aimed at general public must not use images of changes to human body due to a disease or injury or images of the effects of the medicinal product for human use on human body and its parts, in an inappropriate, exaggerated or misleading manner."*	1
§5b para. 5	*"The scope of complimentary refreshments and accommodation* *a)provided on the occasion of a meeting attended by professionals and held for the purpose of promotion of prescribing, selling, dispensing or consummation of medicinal products for human use, or* *b) provided on the occasion of a meeting attended by professionals and held for an expert or scientific purpose,* *must be appropriate, secondary with regard to the main purpose of the meeting, and must not be extended to other persons than professionals; in this case the ban defined in article 4 does not apply to the scope of provided refreshments and accommodation."*	1

Source: the data for the analysis were taken from the report of the State Institute for Drug Control.

Appendix No. 2: Statement of profit and loss of pharmaceutical companies in 2010 (the given data represent the whole group of companies – the multinational corporation) + profit divisible among the shareholders

Amounts given in thousands USD.

2010	Pfizer	Novartis	Meck & Co	GSK	Abbott Laboratories	Sanofi	Eli Lilly
Turnover	67 809 000	51 561 000	45 987 000	44 452 098	35 166 721	42 976 348	23 076 000
Cost of Sales	13 196 000	14 488 000	11 015 000	9 257 722	12 040 887	10 128 654	3 038 000
Gross profit	**54 613 000**	**37 073 000**	**34 972 000**	**35 194 376**	**23 125 834**	**32 847 694**	**20 038 000**
Research & Development Expense	9 413 000	9 070 000	10 991 000	6 978 127	4 037 624	5 904 133	4 884 200
Selling, General and Administration Expense	19 614 000	17 711 000	13 245 000	20 436 504	10 376 324	10 521 726	7 053 400
Operating Income (EBITDA)	**25 586 000**	**10 292 000**	**10 736 000**	**7 779 745**	**8 711 886**	**16 421 835**	**8 100 400**
Depreciation	8 487 000		7 381 000	2 628 736	2 624 305	6 880 777	1 328 200
Interest income	402 000	64 000	83 000	181 616	105 453	140 862	51 900
Other Income (Net)	-3 066 000	2 038 000	-85 000	911 211	72 935	1 608 510	128 600
Special Income/Charges	-3 214 000		-985 000			-1 840 597	-242 000
Interest Expense	1 799 000	692 000	715 000	1 301 059	553 135	626 500	185 500
Profit before taxation (EBT)	**9 422 000**	**11 702 000**	**1 653 000**	**4 942 777**	**5 712 834**	**8 823 333**	**6 525 200**
Taxation	1 124 000	1 733 000	671 000	2 041 615	1 086 662	1 666 197	1 455 700
Net Income from Continuing Operations (EAT)	**8 298 000**	**9 969 000**	**982 000**	**2 901 162**	**4 626 172**	**7 157 136**	**5 069 500**
Net Income from Discontinuing Operations	-9 000					517 835	
Total Net Income from Total Operations (Income attributable to shareholders)	**8 289 000**	**9 969 000**	**982 000**	**2 901 162**	**4 626 172**	**7 674 971**	**5 069 500**

Source: the data were taken from www.forbes.com and from annual reports of the individual companies.

Appendix No. 3: Salaries expenses of selected pharmaceutical companies, which have subsidiaries in the Czech Republic (data were taken from financial statements of the respective subsidiaries)

Amounts given in thousands CZK.

	GSK		Boehringer Ingelheim		Walmark		Walmark - konsolidace		Actavis CZ		Zentiva	
	2010	2009	2010	2009	2010	2009	2010	2009	2010	2009	2010	2009
Obrat	6 169 085	6 187 397	2 220 147	1 982 960	1 162 600	1 282 391	1 971 975	2 000 145	196 461	227 430	1 359 118	1 420 619
Mzdové náklady	**319 928	**332 767	**118 772	**118 385	119 152	137 459	288 554	321 383	39 156	18 209	244 945	384 138
Vedení společnosti	**53 488	**50 753	**19 232	**18 097	22 188	19 837	69 519	70 332	6 541	4 031	88 278	190 558
prům. počet	16	16	5	4	16	14	69	72	4	4	14	23
prům. odměna na osobu/rok	3 343	3 172	3 846	4 524	1 387	1 417	1 008	977	1 635	1 008	6 306	8 285
prům. odměna na osobu/měsíc	**279	**264	**321	**377	116	118	84	81	136	84	525	690
Odměny členů statutárních orgánů a dozorčí rady					1 633	1 620			691	827	12 412	8 894
počet členů					8	8			6	6	9	7
prům. odměna na člena/rok	*	*	*	*	204	203	*	*	115	138	1 379	1 271
prům. odměna na člena/měsíc	*	*	*	*	17	17	*	*	10	11	115	106
Ostatní zaměstnanci	**266 440	**282 014	**99 540	**100 288	96 964	117 622	219 035	251 051	32 615	14 178	156 667	193 580
prům. počet zaměstnance	255	258	83	95	356	414	813	903	32	32	182	215
prům. odměna zaměstnance/rok	1 045	1 093	1 199	1 056	272	284	269	278	1 019	443	861	900
prům. odměna zaměstnance/měsíc	**87	**91	**100	**88	23	24	22	23	85	37	72	75
Mzdové náklady/obrat	5,19%	5,38%	5,35%	5,97%	10,25%	10,72%	14,63%	16,07%	19,93%	8,01%	18,02%	27,04%
Vedení společnosti/obrat	0,87%	0,82%	0,87%	0,91%	2,05%	1,67%	3,53%	3,52%	3,68%	2,14%	7,41%	14,04%
Ostatní zaměstnanci/Obrat	4,32%	4,56%	4,48%	5,06%	8,34%	9,17%	11,11%	12,55%	16,60%	6,23%	11,53%	13,63%

**data not available*

*** including gross salaries, social and health insurance payments made by the employer, other data unavailable*

Source: the data were taken from financial statements of the particular companies available at www.justice.cz.

Commentary: The average gross salaries of employees of the selected pharmaceutical companies are between 20,000 CZK and over 80,000 CZK a month. The average gross salary of the company management goes from 100,000 CZK a month to nearly 700,000 CZK per person per month. The remuneration paid to members of statutory bodies and the supervisory board are between 100,000 CZK a year to nearly 1,400,000 CZK per person per year. ***A funny situation arose in Zentiva in 2009, when the salaries expense of 23 company management members represented 190,558,000 CZK, while the salaries expense of the remaining 215 company employees represented 193,580,000 CZK. In the same year the company paid another 8,285,000 CZK as remunerations for members of the board of directors and the supervisory board.***

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