BELGIAN ADVISORY COMMITTEE ON Bioethics

Opinion no. 64 of 14 December 2015 on the ethical aspects of mandatory vaccination

Content of the opinion

1. Opinion request

This is a self-tasking activity from 12 March 2012, arising from various questions related to the issue of vaccination (mandatory), put forward by Mr A. Pauwels, coordinator of the Superior Health Council of Belgium (CSS):

1. Is it ethically justified for authorities to make certain vaccinations mandatory? If not, why not and in which cases? If yes, why and in which cases?

2. Is it ethically justified for authorities to refuse children who have not been vaccinated access to child care centres? If not, why not and in which cases? If yes, why and in which cases?

3. Is it ethically justified for a person to refuse to be vaccinated? If not, why not and in which cases? If yes, why and in which cases?

4. Is it ethically justified for a parent to refuse to have their child vaccinated? If not, why not and in which cases? If yes, why and in which cases?

The select committee 2012-3 was set up to deal with these questions[1].

[1] Soon after the select committee started its work, it had to adjourn it in order to prepare an urgent opinion on the approach to multi-drug-resistant tuberculosis requested by the Public Health Ministry at the time (Opinion no. 55 of 13 May 2013). When the commission returned to the issue of vaccination (mandatory), it did not have enough time to reach an opinion before the end of its fourth term of office. This is why this issue was examined by the new select committee 2012-3bis during its fifth term of office.

2. Introduction and context

Microorganisms (viruses, bacteria, fungal infections, etc.) came into being much earlier than the higher animal species, including humans. They are an integral part of the living world and there are numerous interactions between these microorganisms and other living beings.

Many of these interactions are useful and necessary (for example, bacterial flora- microbiota - in our colon) but sometimes the interaction between the microorganisms and their host is harmful for the latter and causes an "infectious disease".

Some infectious diseases can be transmitted easily. When people live in a close-knit or predisposing environment, an epidemic may break out.

This is how the first epidemics were able to occur during the sedentarisation of our Neolithic ancestors. Therefore, the existence of epidemics is closely linked to the history (and civilisations) of humans.

Epidemics constituted plagues that determined the origin of the first public health ideas: the organisation and implementation of protective measures with the aim of protecting the community against infectious diseases.

The development of knowledge meant that there was a better understanding of the mechanisms involved: the aggressors - infectious agents - and the victims - human beings - constantly use tools devised from their genes to circumvent the attacker. In this part of the world it has been possible to reduce the mortality rate from infectious diseases throughout the 20th century.

The actions that made this possible:

- related to the environment (e.g. sanitation, housing, supply of drinkable water and waste evacuation);
- reduced vulnerability of humans (food, working conditions and access to health care);
- aimed to neutralise infectious agents (by preventative measures such as vaccinations and medication, for example anti-microbial and anti-viral treatments).

These actions required the involvement of public authorities and mobilised considerable resources.

Today, these resources are cruelly lacking on a worldwide scale. You only have to look at the sanitation conditions in the most impoverished countries where the "simple" lack of drinking

water is responsible for an abnormally high child mortality rate: according to UNICEF[2], 1400 children under the age of 5 still die every day because of the absence of a healthy water supply.

In our countries, the success of the fight against infectious diseases over the past few decades has had the effect of gradually removing these diseases from the collective memory. Current generations no longer live with the memory of having lost a child at a young age to pneumonia or measles, for instance. Healthcare professionals themselves are no longer familiar with certain diseases which have become rare and many of them are too young to have seen them in their professional practice.

This does not mean that the pathogen microorganisms have disappeared from our environment. The sophisticated care that medical progress dispenses to weakened patients also reveals the risks of contracting infections due to opportunistic and multi-drug-resistant germs. We can contract some infectious diseases while travelling and the importation of microorganisms happens owing to trade exchanges and climatic conditions that favour their survival.

This illustrates the need for constant vigilance and the continuation of adequate public health actions to protect us from infectious diseases.

Infectious agents do not stop at borders and due to the internationalisation of the exchange of goods and the speed of human travel, the issue of infectious diseases and the occurrence of epidemic outbreaks must be heeded and understood on an international, if not planetary, scale.

Recourse to vaccination is one of the means of preventing infectious diseases.

Vaccinating against a given disease involves administering to a person not infected with the disease a substance or substances derived from the infectious agent responsible for that disease and which have been rendered harmless. These substances may trigger defensive reactions in the body, called immune responses. The aim is to stimulate the defence system and to induce an immunological memory vis-a-vis the infections agent so that the person is protected when there are subsequent encounters with the agent. The vaccination will prevent the person from falling ill in case of contamination.

The degree and duration of protection depends on the type of vaccine and on the person. This is why there are a number of different vaccination plans which we shall deal with below.

[2] UNICEF: World Water Day, 22 March 2015
http://www.unicef.org/french/
http://www.unicef.be/fr/journee-mondiale-de-leau

We should note here that there are vaccines to prevent infectious diseases caused by bacteria and viruses. The distinction is worth mentioning since, contrary to many diseases caused by bacteria that are treated with antibiotics; the usual antibiotics are ineffective against viruses. Certainly, there are many different antiviral medicines but there is no specific *cure* for diseases such as polio or measles, while these diseases may present serious complications and may lead to grave consequences.

Moreover, the effectiveness of both antibiotics and antivirals is not guaranteed because of the resistance developed by these microorganisms. In addition, they present risks of toxic side effects and can only be administered when the disease is already present. It is for this reason that vaccinations are so important, as they can represent an effective method of *prevention of* various diseases.

As of 13 February 2015, the list of prequalified vaccines by the WHO[3] included 39 types of vaccines to fight against 22 infectious diseases. These 39 types of vaccines are presented in the form of over 200 pharmaceutical specialities put on the market by 29 pharmaceutical companies in the world.

Each country devises its own policy in relation to vaccination. In Belgium, it is the Superior Health Council[4] (CSS) that is commissioned by the public health authorities to issue recommendations and opinions in relation to the vaccination scheme and calendar for our citizens. The CSS prepares the recommended vaccination calendar.

The recommendations that the CSS publish cover 16 diseases in total, including poliomyelitis, for which vaccination is mandatory for all infants unless there is medical contraindication.

"Introduced in Belgium in 1958, the vaccination against poliomyelitis was made mandatory in 1967. From 1967 to 2000 the live, attenuated OPV oral vaccine (Sabin) was used.
Following the occurrence of a case of post-vaccine flaccid paralysis, the vaccine imposed for the mandatory vaccination has been the reinforced inactivated injectable vaccine (IPV) (Salk) (Ministerial Decrees of 18 September and 10 October 2000).
The systematic use of this inactivated vaccine allowed for the elimination of the risk of vaccine-induced paralysis related to the use of a live vaccine.

[3] http://www.who.int/immunization_standards/vaccine_quality/quality_issues/en/
The WHO publishes recommendations and specifications in relation to the quality of vaccines. In this context, the WHO provides a service of prequalification of vaccines for UNICEF and the other United Nations agencies that are likely to purchase vaccines from various sources.
[4] http://www.health.belgium.be/eportal/Aboutus/relatedinstitutions/SuperiorHealthCouncil/?fodnlang=fr
The Superior Health Council is a federal consultation body with the mission of providing the Minister(s) with scientific opinions on public health matters, on which policy in this area may be based. The Council intervenes on request or on its own initiative and also addresses federated and professional entities in the public health arena. Founded in 1849, the CSS has its current legal basis in Art. 36 of the programme law of 27 April 2007 and the Royal Decree (AR) of 05 March 2007 regarding the creation of the Superior Health Council.

The legal obligation to vaccinate against polio necessitates the administration of 3 doses of the vaccine before the age of 18 months: 2 doses with an interval of 8 weeks in the 1st year of life and a third dose between 12 and 18 months.
The existence of combined vaccines explains the variants in the administration plan, without changing the nature and the quality of the vaccine in any way"[5].

In our country, the data collected[6] for the year 2012 indicates as a percentage of the infant population (18 to 24 months), the *following vaccine coverage rates*:

- regarding **the mandatory polio vaccine**:
Polio in 3 doses, according to the regulatory plan:
98.7% in the Brussels-Capital Region (hereafter, Bxl);
98.9% in the Flemish Region (hereafter, CFl);
99.2% in the Walloon Region (hereafter, W).
Polio in 4 doses, according to the regulatory plan: 91.1% in Bxl, 93.3% in CFl and 90.4% in W.

The situation, with regard to the coverage of other vaccines is presented for your information[7].

- Against diphtheria, pertussis (whooping cough) and tetanus (DPT):
DPT 3 doses: 98.7% in Bxl, 98.7% in CFl and 99.2% in W.
DPT 4 doses: 91.1% in Bxl, 93.0% in CFl and 90.4% in W.
- Against Haemophilus influenzae type b meningitis (Hib)
Hib 3 doses: 96.7% in Bxl, 98.7% in CFl and 98.5% in W.
Hib 4 doses: 90.1% in Bxl, 93.1% in CFl and 89.4% in W.
- Against measles, mumps and rubella (MMR):
MMR 1 dose 94.1% in Bxl, 96.6% in CFl and 94.4% in W.

Other vaccinations recommended and included in the calendar published by the Superior Health Council of Belgium

[5] The Superior Health Council, Vaccination Guide D/2009/7795/9
[6] According to the report published by the Scientific Institute of Public Health (ISP)/ Wetenschappelijk Instituut Volksgezondheid (WIV) and entitled 'Paediatric infectious diseases preventable by vaccination'. Annual report, 2013.
The Scientific Institute of Public Health (WIV-ISP) is the scientific point of reference in the public health arena. It provides support for the health policy through its innovative research, its analyses, its surveillance activities and the opinions of its experts.
The Federal Agency for Medicines and Health Products calls upon the WIV-ISP to assess and check the quality of the vaccines and products derived from blood before their commercialisation, in close collaboration with the World Health Organisation and the European Authorities. The WIV-ISP examines the effects of the vaccination in Belgium (against VPH or the human papilloma virus, in particular, a common sexually transmitted virus) and, finally, the WIV-ISP follows the impact of the vaccination on the diseases that figure on the vaccination calendar (like measles or mumps).
[7]The vaccines listed below are recommended in the whole country; for Bxl and W they are, not only recommended, but mandatory for infants who attend an approved child care centre.

Hepatitis B 3 doses: 96.3% in Bxl, 99.0% in CFl and 97.2% in W.
Hepatitis B 4 doses: 89.6% in Bxl, 93.0% in CFl and 89.2% in W.
Meningococcus C 1 dose: 89.4% in Bxl, 93.1% in CFl and 89.6% in W.
Pneumococcal pneumonia 1 dose: 97.0% in Bxl, 99.3% in CFl and 97.1% in W.
Pneumococcal pneumonia 3 doses: 90.1% in Bxl, 96.5% in CFl and 89.2% in W.
Rotavirus 1 dose: 77.3% in Bxl, 94.0% in CFl and 86.5% in W.
Rotavirus (complete): 72.7% in Bxl, 92.2% in CFl and 80.2% in W.

The Superior Health Council of Belgium also publishes valid recommendations for adults and ensures that these recommendations are updated regularly.

The opportunity, usefulness and necessity of vaccinating depend, from a medical viewpoint, on the consideration and analysis of several parameters in the table below.

In fact, for the purpose of a thorough methodology, any decision to pursue a vaccination policy is preceded by a documented analysis of the interactions between the infectious agents, the environment and the person to be vaccinated.

Knowledge of the infectious agent

It is important to know the habitat of the infectious agent (what we call "the reservoir") which could be an ambient environment (drinkable water, for example), one or several animals or a human being. Similarly, we should know how it acts and the way the infectious agent is transmitted to a human being.

Like any living being, an infectious agent evolves by adapting to its new environment, whether it is a case of repeated use of antibiotics or the vaccination status of the population. Thus, new strains may appear and it is important to detect these so that the measures (preventative or curative) taken to fight these infectious agents are effective.

Knowledge of the interactions between the infectious agent and the host

It is important to know the clinical table of the various diseases concerned as well as the various degrees of severity attributable to the corresponding infectious agents. The characteristics of the host (age, state of health, use of medication) may also influence the clinical table.

The characteristics and impact of the infectious agent are important to know in terms of frequency and severity as well as the presence or absence of vulnerable factors in the host.

<table>
<tr><td colspan="4">VACCINE</td></tr>
<tr><td colspan="2">Composition in regard to additives and adjuvants:</td><td>Effectiveness (immunogenic and protective power)</td><td>Suitability
for circulating strain(s)</td></tr>
<tr><td colspan="2">Price*</td><td>Side effects of the vaccine
Incidence and severity:
Contraindications to the vaccination</td><td>Side effects due to adjuvant(s)</td></tr>
<tr><td colspan="4">Feasibility**</td></tr>
<tr><td colspan="4">Vaccination strategies</td></tr>
<tr><td colspan="2">Range of the population</td><td colspan="2">Selective (groups)</td></tr>
<tr><td>Individual protection</td><td>Immunisation
of the population</td><td colspan="2">Protection of vulnerable vaccinated individuals</td></tr>
<tr><td></td><td>Coverage rate required to reach the target.</td><td colspan="2">Protection of vaccinated individuals exposed to specific risks</td></tr>
<tr><td></td><td></td><td colspan="2">Protection of the vulnerable environment of vaccinated individuals</td></tr>
</table>

*It is important to consider this parameter because the high cost of a vaccine may not be compatible with the financial means that the public health authorities devote to preventive medicine.

**The feasibility conditions must be gathered to determine a vaccination strategy. You must be able to ensure the implementation of the vaccination scheme by having the financial means available and having the organisation required to reach the different population groups. It is especially important to ensure that the vaccine calendar is convenient for parents.

Vaccination strategies are devised with three distinct aims:

1) The vaccination should reach the greatest number of people possible to ensure the protection of every individual against the disease; a typical example is the vaccination calendar for infants.

2) Selective vaccination to protect people exposed to particular risks or vulnerable people, for example:
   - vaccination of certain categories of workers exposed given the nature of their work;

- vaccination of people travelling depending on their destination;
- vaccination of people in professional or family contact with individuals such as certain patients, old people, very young infants and even foetuses inside a mother in order to protect them against diseases, against which they lack defences. In these situations, the vaccinations not only protect the people vaccinated but indirectly the vulnerable individuals with whom these people are mixing. Sometimes the term “altruistic vaccination” is used to describe this kind of indirect protection.

3) The vaccination that reaches the greatest number of people possible to achieve collective immunity: the protection of each individual contributes to the defence of everyone, including those who have not been vaccinated, because the immunisation capital constituted on that scale forms a kind of barrier that prevents the infectious agent from spreading. The agent then meets too few sensitive hosts to multiply and thereby spread to other susceptible individuals, develop and so on.

This acquired immunisation among the population constitutes a sort of common good that:

- ensures the protection of vulnerable individuals, those who could not be vaccinated and those who could not produce sufficient defence (such as infants of a very young age, old people, the sick, etc.); we should mention here the particular situation of children whose immunity has been compromised by heavy treatment such as chemotherapy and immunosuppression: these children need immunity acquired through the vaccination of all the other children to be protected against a particular disease;

- contributes to the reduction of social inequalities (for people who have not had access to vaccines): circulation of the infectious agent is so hampered that the probability of a sensitive individual being contaminated is greatly reduced;

- helps to avoid the higher spending that would be required if an epidemic broke out.

To reach this collective immunisation objective, the vaccine coverage among the population must, depending on the diseases, reach 85 to 95%. Care needs to be taken to ensure that this rate is indeed reached among all population sub-groups so that there does not remain a sensitive and conducive “fertile ground”, where the infectious agent may multiply and spread. In any case, the protective effect decreases when less than 80% of the population is immunised. Moreover, the shared immunity heritage must be maintained for the effect to last.

The collective immunisation objective may be reasonably pursued for diseases whose reservoir is exclusively human and when the vaccination programme reaches everybody; a

typical example of this is poliomyelitis[8]. Control (not to say eradication) of poliomyelitis is on course, at the price of constant maintenance of an adapted vaccination. In fact, in some countries where sub-groups are not vaccinated we can see the occurrence of epidemic outbreaks, thus showing that the microorganisms reinstate themselves if they are not opposed by active resistance.

In all disciplines dealing with the living, no option has a guarantee of being 100% effective, nor is it possible to have 0% side effects. However, a methodical and rigorous analysis allows for informed choices.

Certain vaccinations may, in rare cases, cause serious side effects. We could then conclude that administering the vaccines is not justified. However, similar complications may be seen in people who contract the disease, with a frequency of 100 or even 1000 times higher than that which follows the vaccine administration. Nevertheless, even if the risk associated with the vaccine is low, it is never certain that people who are not vaccinated will contract the disease and so will be exposed to a much higher risk. For this reason, complications caused by a vaccine may be considered by some as avoidable in a certain perspective of risk evaluation The much higher frequency of complications caused by the disease is a decisive factor in this evaluation to vaccinate in any case.

When vaccination becomes a public health policy, because it is a question of ensuring the protection of the whole population or some groups that are particularly vulnerable or exposed to certain serious diseases, it is important for the public health authority to broadcast appropriate information so that the largest possible number of the target population comply. This is because the objective to be attained is linked to the maximum vaccine coverage among the population in question so as to ward off these diseases.

A well organised vaccination policy is effective and the probability of contracting the disease or being affected by it diminishes or even disappears.

When the danger ceases to be apparent, it is understandable that, for some people, the vaccination no longer seems to be necessary. The same happens when the anticipated objectives of a vaccination are not reached and the disease resurfaces.

The aspects that relate more to the calling into question of the vaccines will be developed in the chapter on Social and political considerations.

[8] On 26 May 2012, the World Health Assembly of the World Health Organisation adopted a resolution (WHO 65.5) with the aim of eradicating polio in the context of a strategic plan for 2013-2018.

The table sums up the programme of work that should accompany any implementation of a vaccination policy, in its standard acceptance.

OBJECTIVES of a vaccination policy	Protection of citizens against the disease in question.
	Reduction in the rate of transmission of infectious agents among the population.
	Reduction of social equanimities in the area of health* Assignment of public health resources in the most effective manner possible.
*Any health policy should not only be based on sound scientific knowledge and be independent of any commercial pressure, but it should also ensure that all citizens benefit from it, regardless of their education level or their socio-economic means. This entails actions that are adapted to the needs of groups of people who are the most difficult to reach.	
Public health assistance programmes:	
AIMS	To evaluate the effect of policy measures undertaken to bring about necessary improvements
	To reduce the incidence of disease and thereby reduce avoidable morbidity and mortality.
	To reduce the circulation of pathogens
	To limit the spread of epidemic outbreaks
ACTIONS	Organise the vaccination in a manner that the whole target population may be able to benefit from it
	Raise awareness and support the health personnel involved
	Provide sufficient information to the target population (and beneficiaries)
	Carry out research in order to have better knowledge of the pathology in question and the immunisation mechanisms
	Monitor the circulating strains
	Keep a record of the immunisation induced among the population
	Keep a record of the incidence of the disease
	Detect residual or re-emerging cases early

In our part of the world, diseases that can be avoided by vaccination have become rare. Their incidence is currently weak. Consequently, it is important to carry out the following at international level:

- monitoring of the surveillance of the strains of microorganisms in circulation and their development;
- surveillance of the occurrence of the diseases to have a good idea of the way they appear, what determines them and how serious they are.

Similarly, joint or collaborative studies on the vaccines should be carried out between countries to measure the development of their effectiveness and list the side effects. As the occurrence of side effects is not frequent, it is necessary to be able to analyse the data on the basis of millions of doses administered and thus know the real extent of the harm.

3. Social and political considerations

Any measure taken by the public health authorities must be understood by the public that it addresses.

News reports, particularly in the press[9] refer to a questioning of opinion with regard to vaccination policies.

3.1. Summary of a few basic ideas

The state of health of a population includes its immunity status in relation to threats of infection. This is how we can describe the immunity of a population. It is something shared that protects each individual better than each one could do for themselves. It is a common heritage which can only be obtained through the active contribution of each individual with the benefits being shared by all. This living heritage must be maintained because it ceases to act as a protector of the weakest and most exposed as soon as the proportion of contributors falls below a critical level.

Public health intervention in the form of vaccinations is justified if it is an adequate response (that is scientifically well founded), feasible (achievable in terms of organisation and means) and acceptable.

The acceptability of an intervention depends on the perception of its usefulness, of the understanding of its merits and the individual take-up. However, individual acceptability will not suffice: the take-up must also be based on alterity and the common interest of the society we live in, in other words, solidarity.

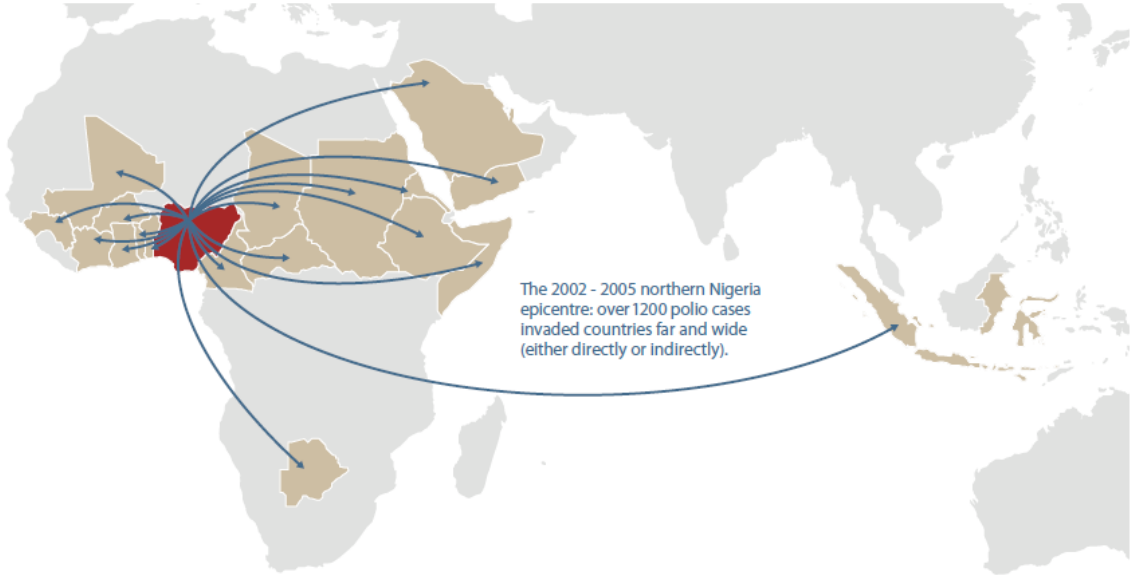
The notion of an epidemic has evolved through history and the technological advances that our civilisation has made. Currently, most epidemics are not as massive and devastating as in times past. These are limited outbreaks in terms of location (for example a few cases of Hepatitis A at a school or remote contagions (due to the speed of travel and the mobility of people and goods that are potential carriers of pathogens), as can be seen, for example, by the growing epidemics of imported measles. In consideration of this mobility factor, we should be prepared to have to deal with epidemics coming from other countries.

[9] "No mandatory vaccination in pre-primary education" in the *Journal du Médecin* of 27 March 2015, "Reduce benefits to enforce vaccination?" in *Le Soir* of 14 April 2015, "Wie zijn kind niet vaccineert, draagt een grote verantwoordelijkheid", interview with Pierre Van Damme in *Knack* of 22 April 2015, "We are paying the bill for paternalism" and "Vaccines should be discussed" in *Le Monde* of 01 July 2015 and "Sentimental medicine – Why we still fear vaccines" by Eula Biss in *Harper's Magazine* of January 2013.

3.2. News and recent contexts

To illustrate a contemporary form of epidemic, we only need recall that the boycott of the polio vaccination in Nigeria for 11 months from June 2003 had the effect of increasing fivefold the number of polio cases in the country between 2002 and 2006 and of spreading the virus beyond its borders, as the figure below shows.[10]

Figure 1: 'A warning from history': How the polio virus escaped the GPEI



Published originally in the November 2012 Report of the Independent Monitoring Board of the GPEI, this figure presents the spread of poliovirus from Nigeria following the 2003-2004 boycott. The IMB aptly titled its figure "A warning from history."
Source: IMB. 2012. Sixth Report of the Independent Monitoring Board of the Global Polio Eradication Initiative: November 2012. Page 11. Available at: http://www.polioeradication.org/Portals/0/ Document/Aboutus/Governance/IMB/7IMBMeeting/7IMB_ Report_EN.pdf [Accessed 19 March 2015].

Such precise analysis of the spreading phenomena was made possible using the current methodology for epidemiological investigation. There is a surveillance system to detect the outbreak of unusual diseases and to "track" their transmission itinerary using sophisticated analyses of microorganism strains present, in order to get back to the source of the problem.

This situation in Nigeria had the effect, among others, of delaying the completion of the WHO project of neutralising polio on the planet. It also instigated investigations into understanding the elements that contributed to the boycott of the vaccination.

Over the past century, the academic and scientific world has been enriched through a multitude of knowledge which has led to medical innovations, from which the population has obviously benefited, but without scientists - or rather "those in the know" - giving much thought to the role patients play in their own health. Since a given technique, medication or

[10] The State of Vaccine Confidence 2015 - The Vaccine Confidence Project, London School of Hygiene and Tropical Medicine, Lead authors: Heidi Larson and Will Schulz (http://www.vaccineconfidence.org/The-State-of-Vaccine-Confidence-2015.pdf)

vaccine is good for your health in the eyes of the custodians of knowledge, they would not be subjects for discussion. The main effect of this form of paternalism, which has not completely disappeared though the principle has been discarded nowadays - as in the law on patient rights - was that the knowledge was only shared among insiders. The horizontal aspect of the communication was also restricted to the learned community. In regard to the general public, communication – insofar as we can call it "communication" in this type of relationship between doctor and patient - was, on the other hand, a mainly vertical method of communication.

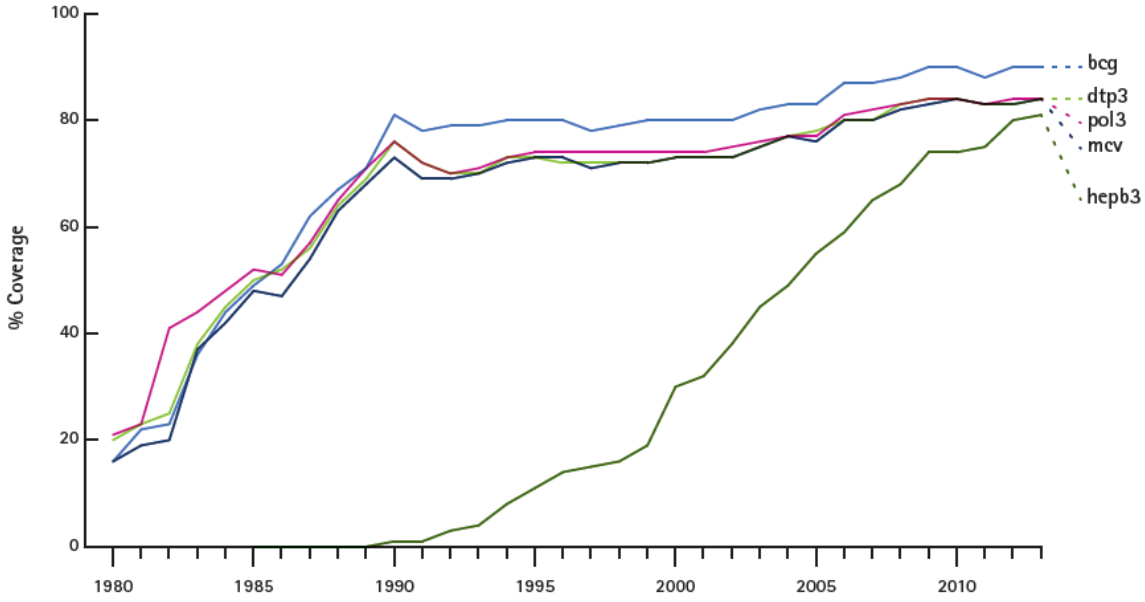
Furthermore, for several decades, the modern world has been characterised by an extraordinary, immediate, general and global extension – reaching the most remote areas of the planet. There is also ever-increasing communication, characterised by its horizontal nature and anonymity, a sort of cloud where assertions are often made without any authentication and where rumours dominate as they are spread by so many. These rumours are the vehicle for mistrust of all institutions and tend to inflate that mistrust. These stories may be based on proven examples of industrial practices or questionable policies which, in the eyes of the general public, increase their credibility.

In the matter at hand, it is incumbent upon us to examine the elements that determine the choices that parents make when it comes to vaccinating their children.

In 40 years, the number of vaccines available has risen from 6 to 16.

The vaccine coverage rate has also increased, as can be seen in the following diagram[11]:

Figure 2: The global rise of vaccines since the launch of EPI



WHO/UNICEF global coverage estimates for selected vaccines from 1980–2013, as of July 2014, presented as percentage of the target population that has received each vaccination.
Source: WHO. 2014. WHO/UNICEF estimates of national immunisation coverage.
http://www.who.int/immunization/monitoring_surveillance/routine/coverage/en/index4.html, accessed 9 March 2015.

("EPI"= expanded programme of immunisation)

In parallel, forms of hesitancy[12] about vaccines, even opposition to them, have arisen to denounce or dispute vaccination policies[13]. One of the factors that escalated this hesitancy is the sceptical attitude of some health care providers in relation to a growing number of vaccines and the different forms in which they are presented. Therefore, in their referring role in the eyes of the patients, their position can influence the choice of parents. Besides, even if they are in favour of the vaccines, they can seem indulgent[14] when parents ask to postpone or not to proceed with a vaccination, which they do in order not to jeopardise the relationship of mutual trust.

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[11] ibidem
[12] The word 'reticence' is used here to translate the idea of "(vaccine) hesitancy" from English. A word with a fairly broad meaning is needed to cover several ideas at the same time: the continuum of attitudes towards vaccines ranging from hesitation to categorical refusal and all the components that come into play in a given attitude.
[13] Larson Heidi J et al. Addressing the vaccine confidence gap. *The Lancet*, August 6, 2011, vol. 378, issue 9790, 526-535, Luyten J. et al. Kicking against the pricks: vaccine sceptics have a different social orientation. *Eur J Public Health*: 2014 Apr;24 (2):310-4, Dubé E et al. Vaccine hesitancy – an overview. *Human Vaccines & Immuntherapeutics* 9 :8, 1763-1773 : August 2013, Yacub O et al. Attitudes to vaccination: a critical review. *Social Science & Medicine* 112 (2014) 1-11, Jarrett C et al. Strategies for addressing vaccine hesitancy – a systematic review. *Vaccine* 2015 Aug 14;33(34):4180-90.
[14] Kempe A, O'Leary ST, Kennedy A, Crane LA, Allison MA, et al. 2015. Physician Response to Parental Requests to Spread Out the Recommended Vaccine Schedule. *Pediatrics* 135(4). See: http://www.ncbi.nlm.nih.gov/pubmed/25733753

For several years, such forms of hesitancy have multiplied and have caused outbreaks of diseases to reappear in these countries where diseases such as polio and measles had previously been under control.

3.3. Studies and observations

The impact of this hesitancy regarding the immunisation of populations has, since 2011, been a cause for worry for the group of experts known as SAGE ("Strategic Advisory Group of Experts on Immunization"), who drafted a report[15] based on the main studies on the mechanisms at play, depending on the context in which these protests happened.

So it is that fundamentally, acceptance (which was mentioned previously and the contrary, hesitancy or refusal) of a vaccine (and hence its absorption, for example, by oral or nasal means or its inoculation by injection) relates to three types of factors: convenience, judgement (or the grounds on which judgement, feeling or appreciation is based) of its usefulness (complacency) and confidence.

Vaccine *convenience* is measured by the availability of resources, the product and equipment, organisation of the vaccination, how the costs are covered and ease of access for parents.

Complacency regarding usefulness supposes among other things that the vaccination against a given disease is considered less important than other priorities. In order to illustrate this point, we'll examine the situation in Nigeria when certain populations protested against the free availability of polio vaccines, a disease for which the risk is considered relatively minor, whereas there was a shortage of other basic health resources such as pain killers, rehydration solutions to treat enteritis, antihelminthics and mosquito nets. Mothers felt there were more fundamental needs and priorities for the immediate wellbeing of their children.

We must refrain from thinking that the people who are hesitant regarding vaccines are not educated. It is because they were aware of their needs that they concluded that the vaccination campaigns were not adapted to their priorities.

From the public's viewpoint, confidence concerns:
- the effectiveness and safety of the product (most parents are asking for more science and proof as to the long-term safety of the vaccine);
- the competence, motivations and exemplary nature of the healthcare professionals that administer the vaccine and
- the soundness of the decisions made by the public authorities that set the vaccination

[15] Report of the SAGE Working Group on Vaccine Hesitancy (WHO), 1 October 2014 (http://www.who.int/immunization/sage/meetings/2014/october/1_Report_WORKING_GROUP_vaccine_hesitancy_final.pdf).

regulations and schedules.

The result is that doubts about any of these 3 factors create mistrust and spill over negatively onto acceptance of the vaccination.

To explain these factors, the studies - cited in the SAGE reports and "The State of Vaccine Confidence" referred to above - enabled us to pinpoint the factors determining the grounds for hesitancy about and even refusal of vaccinations.

For instance, in the literature we can distinguish 3 groups according to: a) the socio-cultural and political context, b) the perception by people and those surrounding them, c) the product – vaccine – and the vaccination.

In the 1st group, in particular, we find consistency in the policy and the instances that support the immunisation programmes, the media environment, lobbies, cultural and historic influences, socio-economic situations and the perception of the pharmaceutical industry.

In the 2nd group, we find: the experience or the previous incidents (personal or experienced by people who are close) of harm in relation to a previous vaccination, beliefs and attitudes in regard to health and prevention, knowledge and consideration, trust in the health system and health care professionals, intuitive judgement in relation to risks and advantages of the vaccination, not understanding what the immunisation represents and regarding it as useless and not as a social asset.

In the 3rd group, we find: the conclusive data of the report on risks (vaccine/disease), the way of administering it and the reliability of the products, the schedule and the vaccination programme, the introduction of a new vaccine or new recommendations regarding the formulation or timing of existing vaccines; the strength of the recommendations and the attitude of health care professionals.

Various research has been carried out on the movements of refusal that have been expressed throughout the world. They have highlighted the grounds and motivations that greatly surpass the strictly medical aspects.
To give just one example, in Pakistan in 2012 the opposition forces (the Taliban) banned antipolio vaccination campaigns[16] by weighing up the Western willingness to do good by spending large sums of money on the vaccination while at the same time waging war by, among other things, flying drones over their territories and thus causing the deaths of hundreds of children.

All contexts, including political and religious are important to consider when we think about the implementation of successful vaccination strategies.

[16] The State of Vaccine Confidence 2015, *o.c.*, p. 18.

Based on all the mechanisms at play, adapted strategies can be deployed so that the vaccination programmes achieve their objectives. An example of an adapted strategy was to include with the vaccine other products that met the primary needs expressed by mothers in the high risk regions of Nigeria, such as the distribution of oral rehydration salts, soap, painkillers, etc.

3.4. The confidence of people in vaccinations

While recognising the interpenetration of the three above-mentioned factors, we shall retain the factors that come into play when determining trust. The reason for this is that the protest movements which our country has confronted criticise the effectiveness and safety of the products, the independence of scientists and the autonomy of the decision-makers in relation to the industry that puts these products on the market.

The subject that deals with the trust of populations in vaccination needs our attention; the factors that influence that trust must be known in the context in which they are expressed; the people must be recognised for who they are and what they think.

When real or so-called problems are debated in the press or social media, an announcement made by a specialist on the subject and known to the public, that "the benefit is an unquestionnable fact" is not sufficient to convince the population, to overcome mistrust or to clarify any confusion.

The studies carried out and cited above, bring us to make a clear distinction between parents who obstinately refuse the vaccination and those who are hesitant. The vast majority of the latter allow their children to be vaccinated but given the lability of their compliance, they are likely to refuse if further problems are raised in the press or on social media, unless measures are adapted for them.

The hesitancy with regard to vaccination has been studied and is based on specific and different mechanisms depending on the population groups and where they live.
A survey[17] carried out in five countries (India, Pakistan, Georgia, Nigeria and the United Kingdom) among parents of children under 5 enabled us to compare the rates of hesitancy and the rates of refusals expressed. The results obtained for our neighbouring country, the United Kingdom, show advanced reasons expressed by parents. In a total sample of 2055 families interviewed, 196 parents had children under 5. Among these, we counted 48 who were hesitant (in other words, 24.5%) Among these 48 hesitant families, we counted 13 refusals (in other words 27.1% of those who were hesitant). The reasons given by all the 48 hesitant families were the following (NB: respondents gave more than one reason):

[17] The State of Vaccine Confidence 2015, *o.c.,* Chapter 3, p.25.

21 did not think the vaccine was safe;
7 had been told by someone else that the vaccine was not safe;
8 had a bad experience or reaction with a previous vaccination;
6 had been told by someone else that their child had a bad reaction;
3 had a bad experience that led to being admitted to hospital;
8 did not think the vaccine was effective;
11 did not think the vaccine was needed;
This category of reasons concerns the safety of the product and undesirable effects.

2 were not able to travel to the place of vaccination;
2 could not go as the timing was inconvenient;
1 was too far away.
This category of reasons is about convenience.

2 had other beliefs (alternative medicine);
1 cited religious reasons.

This study showed that most of the objections focused on the vaccine and its effects, while some had problems with regard to access to the place. A tiny minority gave ideological (2/48) or religious (1/48) reasons.

4. Legal framework

Without claiming to be exhaustive, this chapter on one hand lists the various international, European and Belgian standards, and on the other, summarises the position of judicial case law. Finally, the chapter will end with a number of considerations.

4.1. Rules of International Law

Several rules of International Law, of different legal forces and of different fields of application intended for different subjects make up the legal network.

Thus the **International Health Regulations (IHR) adopted under the auspices of the WHO in 1951** and made mandatory in Belgium in 1952 organise fast information exchange in urgent public health cases (especially epidemics). They also provide for the adoption of measures to combat and control epidemics whether these measures are general (sanitary installations, disinfection procedures, etc.) or individual (isolation of persons, vaccinations, calls for health checks either on arrival at or departure from ports or airports, etc.)
This effort to reinforce international health safety is also the objective of the decision of the European Parliament and the Council of 22 October 2013 on serious cross-border threats to health. This decision provides for different actions to ensure a high level of protection of human health, ranging from the organisation of a system of detection and surveillance of diseases to grouped purchases of vaccines. It was executed by the Commission on 25 July 2014 and, for that matter, refers to the IHR. Each Member State is therefore required to monitor the cross-border dimension of its action plans and, from now on, their European coordination. The competence of each Member State remains in effect complete since in terms of healthcare organisation, the European Union acts by virtue of the principle of subsidiarity.

The International Covenant of 19 December 1966 on Economic, Social and Cultural Rights (*Belgian Official Gazette* of 6 July 1983) in its Article 12 provides that:
"1 The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.
2. The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for:
[…]
c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases;"

The **Convention of 20 November 1989 on the Rights of the Child** (*Belgian Official Gazette* of 17 January 1992), which was adopted in Belgium by the law of 25 November 1991, lists

these principles for children in the following articles:

Article 16

"1 No child shall be subjected to arbitrary or unlawful interference with his or her privacy, family, or correspondence, nor to unlawful attacks on his or her honour and reputation.
2. The child has the right to the protection of the law against such interference or attacks. "

Article 24

"1 States Parties recognize the right of the child to the enjoyment of the highest attainable standard of health and to facilities for the treatment of illness and rehabilitation of health. States Parties shall strive to ensure that no child is deprived of his or her right of access to such health care services.

2. 2. States Parties shall pursue full implementation of this right and, in particular, shall take appropriate steps:
[…]
(f) *To develop preventive health care*, guidance for parents and family planning education and services. (Our italics)
[…]"
Thus this Convention makes provision for obligations on States Parties to recognise the right of the child to the enjoyment of the highest attainable standard of health and to facilities for the treatment of illness. They must also take the appropriate steps to develop preventive healthcare treatment which includes vaccination.

At European level, the **European Convention on Human Rights (ECHR)** is the most influential legal source, especially through its *Article 8*:

"§1. Everyone has the right to respect for his private and family life, his home and his correspondence.
§2. There shall be no interference by a public authority in the exercising of this right except such as is in accordance with the law and is necessary in a democratic society in the interests of national security, public safety or the economic wellbeing of the country, for the prevention of disorder or crime, *for the protection of health* or morals, or for the protection of the rights and freedoms of others." (Our italics)

This Article, which is directly applicable in Belgian Law, therefore, recognises that everyone

has the right to respect for his private and family life. The public authority may only depart from this by way of a law which, in a democratic society, is necessary for the protection of the health or the protection of the rights and freedom of others. It is mainly in the respect of these conditions that the polio vaccine is mandatory in Belgium.

4.2. Belgian law and regulation

In Belgium, several federal and community laws deal with this issue. The Federal Authority is competent to organise a vaccination (national preventive measures) by virtue of a special law of 8 August 1980 (article 5, §1, I, par.2, 2°) on institutional reforms. By virtue of this Article 5, the Communities have authority in regard to health education as well as activities and services of preventive medicine. The Federal State also has authority in matters of labour law and social security.

On 29 March 2000 a protocol agreement was made in regard to prevention and, in particular, the vaccinations against poliomyelitis and Hepatitis B (*Belgian Official Gazette* of 29 August 2000). Similarly, on 20 March 2003 (*Belgian Official Gazette* of 13 June 2003) and 28 September 2009 (*Belgian Official Gazette* of 29 October 2009 – ed. 2) the Federal Authority and the Communities signed a protocol agreement on prevention.

This is why since 1 January 1967 the only mandatory vaccination in Belgium is the anti-polio vaccination by virtue of the Royal Decree of 26 October 1966 *(Belgian Official Gazette* of 06 December 1966),[18] taken in execution of the health law of 1 September 1945.

This obligation is based on considerations of public health, which is part of public order.[19]

The series of vaccinations should begin from the fourth month of life and be finished by the end of the 18th month of life. Initially the live, attenuated OPV oral vaccine was used (Ministerial Decree of 27 October 1966). From 1 January 2001, the oral vaccine was replaced by the inactivated injectable polio vaccine (IPV) and the first injection was brought forward to the age of 2 months (Royal Decree of 22 September 2000 (Belgian Official Gazette of 28 October 2000) and Ministerial Decrees of 18 September and 10 October 2000).

When the series of vaccinations is complete, the doctor must issue a certificate to the parents who must then present it to the communal administration in the area where they live.

[18] The official coordination in the German language appeared in the Belgian Official Gazette of 16 June 2014.
[19] See Genicot G., *Droit médical et biomédical (Medical and Biomedical Right)*, Brussels Larcier, collection of the Law Faculty of the University of Liège, 2010, p. 142-144 and the literature cited therein.

The Royal Decree of 26 October 1966 obliges each municipal administration to make a declaration to the FPS Health, Food Chain Safety and Environment. The Mayor is responsible for submitting every month a list of children who have reached the age of 18 months and for whom he has not received a vaccination certificate. This does not always mean that the child has not been vaccinated but it may be that the parents forgot to send the doctor's certificate to the municipal administration. After three reminders, which include raising the parents' awareness of the importance of this vaccination, the file is sent to the Public Prosecutor[20]. Parents who do not fulfil their obligations may be penalised. Article 8 of the Royal Decree of 26 October 1966 specifies that "*violating this Decree is punishable by the penalties provided for by the Health Law of 1 September 1945*". These penalties are enacted in Article 5 of the Health Law: "*Violating the terms of this law and the regulations enacted for its execution are penalised by a fine of between 26 and 100 francs [21] and imprisonment of between eight days and one month or by one of this penalties only. In the case of a repeat offence within two years of the first sentence, these penalties may be doubled".*

The Commissions médicales provinciales (CMP) (Provincial Medical Commissions) have a "polio" database for children under 6 years old. According to this, about 1% of children have not complied with the polio vaccination guidelines. In most cases, this is due to forgetting to submit the documents or an incomplete vaccination. Deliberate refusals only represent a very small percentage[22].

A Royal Decree of 2 December 2015 extended the suspension of the mandatory anti-smallpox vaccination until 31 December 2026[23], in particular since the eradication of smallpox was officially proclaimed and confirmed by the WHO.

Mandatory vaccinations are also planned in particular areas such as work relations and international travel.
Thus, the Royal Decree of 4 August 1996 relates to the protection of workers against risks associated with exposure to biological agents at work and provides for mandatory vaccination for workers exposed to various risks of contamination (tuberculosis, hepatitis).

[20] Response to Parliamentary question no. 924 from Deputy Luk Van Biesen of 20 March 2013 (N.) to the Deputy Prime Minister and Minister for Social Affairs and Public Health, in charge of Beliris and the Federal Cultural Institutions («*La vaccination obligatoire contre la polio (Mandatory polio vaccination)*», QO 15774, DO 2012201312135).
[21] The amounts in Belgian francs have been converted into euros since 2012 by multiplying by 6. E.g.: a fine of100 Belgian francs =100 euros multiplied by 6 = 600 euros.
[22] Response to Parliamentary question no. 924, *o.c.*
[23] Royal Decree of 2 December 2015 extending the suspension of the application of the Royal Decree of 6 February 1946 which made the anti-smallpox vaccination mandatory (Belgian Official Gazette of 22 December 2015).

There is also provision made for mandatory vaccination against certain diseases for people who travel by virtue of the International Health Regulation made mandatory in Belgium by the Royal Decree of 29 October 1964 on the health policy of international traffic. Proof of vaccination may be demanded as a condition of entry to certain states.

A number of decrees have been enforced by the Communities within their area of competence and useful extracts can be found in an annex. Focusing on different aspects, these decrees, ordinance laws and orders set the applicable regime within the framework of preventive care acts and for pre-school centres and schools. For instance, the Flemish Community has provided for vaccination schemes but without making them mandatory in pre-school centres, while pointing out that the objective is to reach the highest level of vaccination possible. It insists on the individual responsibility of each person in relation to their own health and also in relation to the health of their neighbour with a personal obligation (but without further definition) to comply with the preventive care programmes. The French Community on the other hand has provided for a mandatory vaccination through ONE (Birth and Child Office) in all centres attended by children (it should be noted that all forms of centre - including crèches - are subject to authorisation). In the case of medical contraindication of the child, he or she will not be authorised to attend the crèche without the authorisation of a doctor from ONE. In the case of an epidemic - especially of whooping cough in school - a child who has not been vaccinated will have to leave the school for a fixed period of time. The German-speaking community enacted its new regulations in 2014 and is already planning its modification to make vaccination mandatory as it is currently only advised in nurseries and schools.

The **Patient Rights Law of 22 August 2002** (Belgian Official Gazette of 26 September 2002) must also be considered and - after listing the applicable terms - we are going to examine the way case law has interpreted them in conjunction with other mandatory legal terms.

Article 8

"§ 1. The patient has the right to freely consent to any procedure by a professional practitioner subject to prior information.
This consent is given explicitly, except when the doctor, after having clearly informed the patient, may reasonably infer from the behaviour of the patient that he is consenting to the intervention.
On the request of the patient or the medical practitioner and with the agreement of the patient or the medical practitioner, the approval is established in writing and added to the patient file.
§ 2. The information given to the patient, within the framework of his consent as in § 1, relates to the purpose, nature, degree of emergency, duration, frequency, contraindications for the patient, side effects and risks related to the intervention, after-care, possible alternatives and financial consequences. It also relates to the possible consequences in case of refusal or withdrawal of the consent, and any other details deemed desirable by the patient or the doctor and where appropriate the legal terms that must be respected in relation to the intervention. "

Article 10

"§ 1. The patient has the right to protection of his private life during any procedure performed by a professional practitioner, especially with regard to information about his health.
[…]
§ 2. No interference is allowed in the exercise of this right unless this is provided for by law and *is necessary for the protection of public health* or for the protection of the rights and freedom of third parties" (Our italics)

Article 12
"§ 1. If the patient is a minor, the rights set down by this law are exercised by the parents exercising authority over the minor or by his guardian.
§ 2. Depending on his age and maturity, the patient is involved in the exercise of his rights. The rights listed in this law may be exercised autonomously by the minor patient who may be considered apt to reasonably understand his interests."

Article 15
[…]
"§2. In the best interests of the patient and to avert any threat to the patient's life or his/her health being seriously affected, the healthcare practitioner and where applicable the multidisciplinary consultation may deviate from the decision made by the person referred to in Articles 12 and 14, § 2 or 3. If the decision was made by a person referred to in Article

14, § 1, the healthcare practitioner may only go against this to the extent that this person cannot invoke the express will of the patient."

Considering the very young age of the child at the time of the vaccination against polio, it is the parents who are going to exercise its rights without any association of the child. The Belgian Advisory Committee on Bioethics (CCB) already had the opportunity to point out - especially in its Opinion no. 16 of 25 March 2002 on the refusal of a blood transfusion by Jehovah's witnesses and no. 44 of 23 June 2008 on inhibition of growth in children with very severe mental handicaps - that it is the interests of the child that the parents should be considering. Parents should keep in mind the expected benefit for the child, especially by avoiding any threat to the child's health or life and should not be seeking their own interest only. It is possible to refer to the judge for children to control the correct execution of their duties by parents: the judge may pronounce educational assistance (Article 31 of the law of 08 April 1965) or more serious measures (Article 32).

Finally, we must remember that it is a mandatory vaccination that is imposed on the parents, unless a medical exception has been made due to the state of health of the child.

Indeed, this is how the Conseil constitutionnel français (French Constitutional Council) handed down its decision on 20 March 2015. A request to examine the constitutionality of a case was submitted to this Council by parents who had refused to have their daughter vaccinated. The request was formulated as follows: "are the provisions of the Penal Code, that provide for and penalise non-compliance with the mandatory vaccine, contrary to the preamble of the Constitution of 1946 (...) on rights to health, in that these provisions impose a vaccine obligation on those who have parental authority over their minor children and forbid them to be exonerated in view of the real or supposed dangers of the said vaccinations?" As well as implementing decisions necessary for the protection of health should the State not also ensure that it does not act in a way that goes against the health of the population[24]? It was the theory of the parents that they were safeguarding the health of their child by refusing to have her vaccinated.

The French Constitutional Council considered that the terms provided for by the law imposing vaccination were not manifestly inappropriate to the stated health objective.
The legislator wishes to combat very serious and contagious diseases and thus to protect individual and collective health. These terms may also be modified to take into account any development in scientific data. The legal clauses providing for the mandatory vaccination,

[24] Valérie Olech, "The mandatory vaccination is not contrary to the constitutional principle of health protection" *Rev. Dr. Santé*, May 2015 p.482 and following and *RGDM*, June 2015, p.267.

except in the case of medical dispensation, are therefore in compliance with the Constitution.

In Belgium, the same reasoning could be applied to Article 22 bis of the Constitution which states that: "Each child has the right to respect for his moral, physical, psychological and sexual integrity. [...] The interest of the child is primordial in any decision concerning that child. The law [...] guarantees the rights of the child". This matter has not yet been brought before the Belgian constitutional court.

4.3. Jurisprudence: overview of the most frequent means and arguments advanced.

Is the mandatory vaccination against poliomyelitis an arbitrary or unlawful interference with the privacy or family life of the child, as specified in Article 16 of the Convention of 20 November 1989 on the rights of the child?

In the Decree of 1 October 1997[25], the Court of Appeal ruled that the Royal Decree of 26 October 1966 making the antipoliomyelitis vaccination mandatory had been regularly enacted in execution of Article 1 of the health law of 1 September 1945, following agreement by the Superior Council of Public Hygiene, and that mandatory vaccination against poliomyelitis did not constitute an arbitrary or unlawful interference with the privacy or family life of the child, as specified in Article 16 of the New York Convention on the rights of the child, because it is within the framework of taking appropriate measures to combat disease and to develop preventive health care, to which the States committed under Article 24 of that Convention. The Court recalls that Article 8 of the European Convention on Human Rights authorises interference by the public authorities in private and family life, on two conditions; first, that this is in accordance with the law and second, that it constitutes a necessary measure for the protection of health.

Are the mandatory medical school examination and the mandatory vaccination against poliomyelitis contrary to the right to respect for private and family life (Art. 8 ECHR)?

The Ghent Court of Appeal ruled on 20 March 1996 that "the mandatory medical school examination and mandatory vaccination against poliomyelitis are not contrary to the right to respect for private and family life (Art. 8 ECHR). These measures are taken in accordance with the law with a view to protecting the health of the population in general and of young people in particular. (...) The advantages for the community and for the individual that result from

[25] Cass., 1st October 1997, *Pas.*, 1997, I, 923, *Rev. Dr. Santé*, 1998-99, p. 138.

mandatory medical examinations and vaccination compensate for any possible inconvenience to the individual."[26]

Does the Royal Decree of 26 October 1966 contradict Article 8 of the Patient Rights Law of 22 August 2002?

On 16 March 2011, the Criminal Court of Tournai acquitted a couple of parents who had refused to have their child vaccinated against poliomyelitis for reasons of allergies, underlining the incompatibility between the Royal Decree that makes the antipoliomyelitis vaccine mandatory and the Patient Rights Law of 22 August 2002[27].

In an unpublished decision of 25 March 2013, the Mons Appeal Court sentenced the parents to the payment of a fine. The court ruled that "that the health law of 1 September 1945 had authorised the King to prescribe measures (…) to prevent and combat contagious diseases that presented a general danger, as in this instance poliomyelitis". Even if a patient has the right to refuse treatment, the right "is not absolute and especially when the mandatory treatment by a professional is based on considerations of public health protection, which is part of public order (…). The mandatory vaccination against poliomyelitis was introduced with a view to public health protection in order to prevent the development of an extremely contagious disease that could cause serious paralysis, for which there was no cure, and to participate in its eradication worldwide (…). First, the health law and its implementation decree of 26 October 1966 protect the general interest through these measures, while at the same time protecting the individual; by preventing the virus from spreading (...) should take precedence over the private interest of the patient (...)"

The Decree cites a report by the Superior Council of Public Hygiene of 2009 and the WHO site from which it arises that "recent epidemiological data show the need to maintain excellent vaccine coverage and that this applies even in countries where polio has been absent for a long time" and that "in spite of progress achieved (...), as long as there is one child infected by the polio virus, all children in all countries will be exposed to the risk of contracting the disease. The polio virus can be easily imported into a country that is free from poliomyelitis and can then spread quickly among the people who are not immunised. Any failure to eradicate it could result in as many as 200,000 new cases every year, within 10 years, all over the world. The Appeal Court added that "the outcome is that mandatory vaccination always appears justified for the purpose of public health protection and consequently the choice of the Belgian authorities to maintain mandatory vaccination does not seem

[26] Ghent, 20 March 1996, *R.W.*, 1996-97, p. 1257, note Lemmens, *Rev. Dr. Santé*, 1996-97, p. 35.
[27] See Mouton, A., "L'obligation vaccinale : quelques enjeux du débat", (Mandatory vaccination: some issues of the debate), *JDJ*, n° 315, May 2012, p. 28.

disproportionate (…). Finally, even if mandatory vaccination can be seen to constitute interference in the right to privacy, this obligation is dictated by legal clauses and this is a proportioned response to a legitimate objective: the protection of the health of the population at large. (…) As such it does not constitute arbitrary or unlawful interference with the privacy of the child[28] and is not in breach of any other international convention invoked by the accused."

The Court of Appeal had to reach a decision on 18 December 2013 on an appeal of the parent: it rejected the appeal mainly on the following grounds: the Royal Decree in implementation of Article 1 of the health law of 1 September 1945; a vaccine is a preventive measure in the meaning of the law even if it is not regarded as such. Moreover, the law of 22 August 2002 on patient rights does not have the same aim as the health law. While the first protects the rights of patients in their relations with practitioners, the second provides for the possibility of imposing treatment to ensure public health protection. Therefore, there cannot be a contradiction between these two laws. Finally, the right to privacy is not absolute and can be seen to be limited in respect to the conditions of Article 8.2 of the European Convention on Human Rights. In this instance, imposing a mandatory antipoliomyelitis vaccination is an authorised restriction because it is proportioned and meets the objective of public health protection.

Does vaccination constitute interference in private and family life, in the meaning of Article 8 of the European Convention on Human Rights?

The decision of European Court on Human Rights of 15 March 2012 deals with this question through the following case: a person who was vaccinated considers they suffered damage because of the appearance of various diseases linked to the vaccination. He also claimed that medical errors had been committed causing him harm; the doctors had not been attentive to the medical contraindications and the vaccine was defective. The European Court considers that respect for physical integrity falls within the competence of the law on private life. Vaccination is, therefore, an interference with one's private life. Nevertheless, in this case this interference was provided for by law and pursued the legitimate aim of the protection of health. Moreover this vaccination was a necessary act in a democratic society.

4.4. Liability

Being a mandatory act, the question arises as to which liability regime to apply in case of prejudicial side effects for a person who is vaccinated. Penal and civil liability regimes with or

[28] Cass. 1 October 1997, J.L.M.B. 1998, p. 796

without fault may be applied depending on the situation.
In the case of a fault, the onus is on the person who was vaccinated to prove it and the fault could come under two main categories:
- a fault on the part of the authority which may have wrongly obliged a person to be vaccinated due to lack of prudence in its policy;
- or a fault that occurred during the administration of the vaccine by a medical practitioner.
Those who claim to be victims must also prove the causal link between this fault and the damage suffered.

In the context of a compensation regime without fault, the injured person may on the one hand have recourse to the law of 31 March 2010 on compensation for damages arising from healthcare. Depending on a certain threshold of damage to be reached, the medical accident, which must not be due to the state of the patient, must be of an abnormal nature. This nature is recognised when it is something that should not have happened, taking into consideration the current state of science, the state of the patient and the person's objectively foreseen evolution.

On the other hand, this person may have recourse to the law of 25 February 1991 concerning liability in relation to defective products by proving the vaccine defect and the link between the damage suffered and the defect.

Finally, the Council of State may, ruling on an equitable basis, compensate any exceptional damages caused by an administrative authority (Article 11 of Consolidated Laws). A ruling of the Appeal Court of 28 November 1997[29] illustrates this in a case of mandatory vaccination for serious and exceptional damage which had not been compensated on the grounds of liability with fault.

4.5. Final considerations

The standards which were examined in this way show the extent of the regulation of public authorities in this area. The aim is to restrict the mandatory nature to the necessity of protecting public health from contagious pathologies for which there is no cure, as is the case for polio. These mandatory measures must be provided for in law and cannot be left to an executive body. They must be re-examined periodically according to epidemiological and scientific data in order to obtain the correct response for the protection of public health. Finally, being a mandatory or recommended measure, the legislator should improve regulation regarding compensation for prejudicial side effects. In effect, where the community

[29] *Pas.* 1997, p . 1251 and following.

protects itself by vaccination, it is its obligation also - through justice and solidarity - to compensate damages suffered by one of its members in the case of an undesirable medical effect. A specific compensation scheme would, therefore, be welcome.

5. Ethical considerations

5.1. Aim of ethical reflection

The considerations expounded below relate to the four questions put forward to assess any possible restrictive characteristics of certain vaccinations under quite specific conditions. The instances likely to impose an obligation are public, on the one hand, or cover a private aspect, on the other hand.

In summary, the issue raised may be understood as follows: to what extent should the right of self-determination of the individual and his right to physical integrity compromise the presumed collective interest? In this context, we must also not forget the question of minors whose vaccination or otherwise is, in principle, a parental decision.

5.2. Individual and community

There are several very different types of organisation in a society: it may be a structure with strict limits on individual freedom, in other words a totalitarian model, or a diametrically opposed structure, that is a libertarian model, which aims to guarantee maximum individual liberty and to limit interference by the public authorities to the bare minimum. Between these two extremes, there are several mixed structures which give the individual and the community priority in varying degrees. Therefore, there are different choices depending on the type of society organisation. In the area of public health and preventive medicine, there are different grades of directionality that more or less limit the freedom of choice of the individual. One can also refer to the intervention ladder of the Nuffield Council on Bioethics.

The intervention ladder of the Nuffield Council on Bioethics[30]:

- *eliminate choice*: the law eliminates choice completely;
- *restrict choice*: the law restricts the options available to people;
- *guide choice through disincentives:* financial accessibility or other disincentives to influence people not to make certain choices;
- *guide choices through incentives*: financial or other incentives to encourage people to make certain choices;

[30] http://nuffieldbioethics.org/report/public-health-2/policy-process-practice

- *guide choices through changing the default policy:* make the better/healthier choice the *default* option;
- *enable choice*: enable individuals to change their behaviour;
- *provide information*: inform and educate the public;
- *do nothing* or simply monitor the current situation.

For vaccination the choices in the intervention ladder range from mandatory vaccination to optional vaccination with incentives and the absolute free choice of people concerned regarding whether they are vaccinated or not, without any attempt to influence this choice.

Western democracies agree on the importance of respecting the physical integrity of the person, a position that translates into informed consent, which is closely linked to the integrity referred to above in the case of mandatory vaccination. However, this principle is not absolute. In some circumstances it may be necessary to make a vaccination mandatory in order to prevent an imminent risk of serious illness.

5.3. The consequences of infectious diseases and vaccination

Infectious diseases have a strong impact on morbidity and mortality in the world. In this context, vaccination is an important tool, among others in the prevention of infectious diseases. Its general interest, therefore, cannot be denied. This state of affairs provokes discussion on the role that the public authorities should play in the development, promotion and surveillance of vaccines.

The fundamental objective of a vaccination campaign must be to maximise the advantages on the level of preventing morbidity and mortality in all sections of the population and at the same time to assess the potential risks of vaccines, depending on the positive and negative effects. Knowing that no medical act is risk free, we must not lose sight of the fact that the risk of complication is better accepted in the case of the *therapeutic* approach to a sick person than when it is associated with a *preventive* approach, as is the case of vaccination.

In the context of a prevention policy, what is involved, in effect, is the inoculation of a person in good health with an agent that is supposed to lead to the development of the person's immunity against the pathology in question. In very rare cases, the vaccination may also have negative effects (risk less accepted). For most of the usual vaccines, these side effects are however very limited. From a certain philosophical viewpoint, it can happen that these negative effects are also exaggerated, sometimes even for fraudulent purposes. Take, for example, the approach of Andrew Wakefield who falsified data which gave rise to the publication of a dishonest article in *The Lancet* in 1998. In the article it was suggested that there was a link between the administration of the MMR (measles, mumps and rubella) vaccine and autism, inciting mistrust of certain vaccines administered to young children. This fraud

was only proven after about ten years and the paper concerned was denounced and retracted. However, it is very difficult to get rid of false ideas which get lodged in the minds of health workers and the population following this event.

Finally, it is important to reduce the health fracture to the detriment of weak socio-economic groups.

5.4. Usefulness of vaccination

The social usefulness of vaccination depends on the nature of the infectious disease which you are trying to prevent or hinder from spreading further, the target groups, the effectiveness of the available vaccines and the associated potential risks. In addition, it should be taken into account that the vaccine has a direct preventive effect for the patients vaccinated, for the patients and the people around them (for example, the flu vaccine for people working in the healthcare sector) or if it is administered more widely for herd immunity, that is, for immunity among the population of a country against a specific infectious disease. You could even aim for the worldwide eradication of very serious pathologies such as polio or smallpox.

5.5. Individual protection and/or protection of others

In some cases, a vaccination may not only be useful, but may prove to be essential as well. In certain professional situations the administration of a vaccine against tetanus is essential. This would also apply to people travelling to some tropical countries who need to be vaccinated against yellow fever (transmission of the virus by some mosquitoes).

Other vaccinations are used in the context of a pandemic or a local epidemic.

Routine vaccination programmes may have three different aims:

- The first is the protection of the individual through the vaccination of as many people as possible. This is the case for vaccines that are usually administered to young children.
- You can then aim to protect sensitive groups. This is the case, for example, of the administration of the annual flu vaccine to health workers who are in contact with sensitive people such as older people or those who are immunodeficient.
- Finally, a third aim may be the immunity of a population. What qualifies as immunity of the population has the effect that if a contaminated person arrives among a population that has vaccination coverage of 80-90% against a specific infectious disease and comes into contact with individuals already immunised, there is no contamination. This could lead to the disappearance of the infectious agent (for example that of poliomyelitis).

Therefore, the vaccination is in the general interest. This not only plays an essential role in the protection of individuals, but also in preventing the spread of an infection among the population and in compensation of the health fracture between social groups.

5.6. Advantages and risks of the vaccination: assessment

As we have already mentioned, there is no medical act that is risk free. It is for this reason that we must weigh up the advantages of a specific vaccination against the possible risks that could follow it. This evaluation is even more important depending on the nature of the State vaccination programmes: is it a mandatory vaccination? Is it an information campaign with a view to encouraging citizens to have themselves and their children vaccinated against certain pathologies? Or do the public authorities do nothing in this area?

If there is a vaccination programme supported by the public authorities, it is vital that they provide clear and accurate information explaining the usefulness of the specific vaccination and any possible negative effects. It is also important to ensure this information is free from any commercial influence.

When the public authorities impose or strongly recommend a vaccination, it should also repair any damage caused by its possible undesirable effects.

Since a high level of vaccination in a community greatly reduces the probability that an infectious agent will spread to it and the administration of a vaccine by personal choice would be of little interest, there is the possibility that some people will refuse to be vaccinated. This attitude raises an issue from an ethical point of view, since the person directly and automatically enjoys protection to which they refuse to contribute for others. Moreover, if a large group of people take this course, the immunity effect of the population described above will decrease with all the resulting consequences, both for the individual and the community.

It follows from the above that we should weigh up several different elements when assessing the advantages and potential risks of a vaccine before launching a vaccination campaign.

5.7. The approach to vaccination by the public authorities

Comment
This chapter takes its inspiration mainly from the report 'Public health: ethical issues'[31] of Nuffield Council on Bioethics, transposed to the Belgian context.

According to this report, there are three approaches that the public authorities may adopt with regard to a specific vaccination.

1) Mandatory vaccination[32]: the vaccine is mandatory, for individuals or for their children, unless they qualify for an exemption as defined in law; there are penalties for those who do not comply
2) Optional vaccinations with incentives: the vaccination is not mandatory but individuals who comply receive some reward, usually financial
3) Voluntary vaccination: the vaccination is optional and the choice of whether or not to comply does not give rise to any penalties or incentives.

5.7.1. Consequences of mandatory vaccination

Not surprisingly, the above-mentioned report shows that, in general, the coverage rate for mandatory vaccinations is higher than for those that are voluntary. However, this is not necessarily to suggest that mandatory vaccination schemes are more effective than other types. Some of the highest levels of coverage in Europe are seen in countries where vaccinations are voluntary.

Taking a pragmatic view, mandatory vaccination does not necessarily lead to better results.

Mandatory vaccination schemes may result in a lower uptake than optional vaccines (such as in France). Where vaccination is required for school admission it happens that some parents only get their children immunised just before starting school rather than at the recommended age for vaccination. Further questions may be asked over whether the punishments for refusal to vaccinate are legitimate: will fines or refusal of access to education disproportionately affect those on lower incomes?

Even if a legal obligation is imposed with the best intentions, it can lead to mistrust or a hostile attitude towards the authorities among a section of the population.

From an ethical viewpoint, a legal obligation also goes against the values of self-determination and autonomy, values that are held in high esteem in our society. Yet in certain circumstances,

[31] http://nuffieldbioethics.org/project/public-health
[32] In the Nuffield report: the expression "quasi-mandatory programmes" is used to establish a difference with "forcing individuals to be vaccinated" which in all probability means a *manu militari vaccination ...*

an obligation may be justified on an ethical level, if it is the only possibility available to uphold the general interest and the interest of vulnerable people.

5.7.2. Optional vaccination with incentives

Regarding the use of incentives, international studies have found that they have a positive influence on immunisation uptake, although cost-effectiveness varies. Incentives of modest value are less of an issue in ethical terms than higher-value financial incentives. In this kind of scenario, we could wonder if the consent is being "bought"; in other words if it is leading people to take risks they might not take in other circumstances.

Forbidding children who are not vaccinated access to a crèche or a school may be considered as a negative incentive. The choice not to have your child vaccinated has serious practical consequences in this case.

The granting of incentives is justified from an ethical point of view because an incentive may be considered as a reward for contributing to the health of others. A negative element of incentives is that they risk putting an end to altruistic motivations of contributing to the general interest[33].

Lighter types of incentives are often used. These are referred to as "nudges" and they encourage vaccination. The practical organisation of the policy in terms of vaccination has many examples: availability of free vaccines, organisation whereby a vaccine is administered almost systematically (except in the case of active refusal) and with a gift of a sweet or other small present after the vaccination. The aim is to make the vaccination attractive and to reach a stage where it is the standard option (by default).

Some people might however object on the grounds that this strategy could be perceived as manipulation and give rise to theories of plots among those who oppose vaccination[34].

5.7.3. Voluntary vaccination vs. mandatory vaccination

Supporters of a completely voluntary vaccination system base their idea on the importance they assign to individual autonomy and informed consent (you cannot force individuals to take risks no matter how small they are). However, we must not lose sight of the fact that in the context of public health, individual decisions on whether or not to be vaccinated also have an impact on the population as a whole.

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[33] Luyten, J., *Billijkheid, Efficiëntie en Volksgezondheid – Studies in de Ethiek en Economie van een Vaccinatiebeleid* – Proefschrift voorgelegd tot het behalen van de gedeelde graad van doctor in de Medische Wetenschappen aan de Universiteit Antwerpen en doctor in de Wijsbegeerte aan de Katholieke Universiteit Leuven – Antwerp – May 2014,third chapter (See https://www.uantwerpen.be/nl/personeel/jeroen-luyten/publicaties/)

[34] *Ibidem*

This is the reason why supporters of mandatory vaccinations refer to the protection that this scheme represents for the whole population. Mandatory vaccination may even be recommended without necessarily being aimed at achieving immunity for the population. Therefore, mandatory vaccination of healthcare workers against serious diseases could be increased by basing it on J. S. Mill's harm principle and the protection of the community, given that these people risk contaminating their patients. With regard to this, we should point out the importance of their role in the way that a possible epidemic should be approached.

In the classic liberal point of view, the public health policy must always opt for the measure which is the least interventionist in regard to individual freedom. More prescriptive vaccination programmes that go further than information and incentives (see Nuffield Council's intervention ladder) may however be justified from an ethical point of view on the grounds of the reduction in risk and damage for others and the protection of the health of children and other sensitive people. In this framework, a case-by-case analysis will always be required. This will take into account the following aspects:

1) Evaluation of the risk associated with the vaccination compared to the inherent risk of contracting the disease itself.
2) The severity of the danger of the disease for the population.

The Nuffield Council report has already identified two cases where the mandatory vaccination may be indicated:

1) serious and contagious diseases, such as smallpox;
2) serious diseases which are about to be eradicated, such as polio.

Diseases against which vaccination should ideally cover all individuals to achieve immunity for the population, but that do not constitute a significant risk for some of the people vaccinated and for whom, therefore, the vaccination is of no substantial advantage, represent a problem that is difficult to deal with. Take for example the vaccination of boys against rubella or the papillomavirus infection (HPV) and that of girls against mumps. If in these cases everyone acted according to their own interest, prevention would have little - if any - chance of success.

The Nuffield Council report concluded that from an ethical point of view, it is justified to encourage individuals to take part in vaccination programmes when the associated personal advantage is minimal or non-existent, since they represent a significant advantage for others.

5.7.4. Vaccination of children

The report asks that particular attention be given to children because they cannot, in effect, give any informed consent. Only a limited number of children cannot be vaccinated for medical reasons. For all other children, their vaccination or otherwise depends on a parental decision.

We can start out from the principle that is based on the child's best interest (*best interest considerations*). When this is not the case, the public authority may in exceptional cases intervene to safeguard the health of the children.

This best interest regulation is sometimes difficult to apply in certain situations, especially in cases where there is population immunity. This means that the added advantage of the vaccination for the child is very limited, given that in a manner of speaking the child is protected by the immunity of the population. On the other hand, it is in the interest of society that each person contributes to maintaining the global immunity. This is the reason why the report recommends that the best interest approach should not only take into account the needs of individual health, but also the wider public health context and it is advised that appeals should be made to parents to have their children vaccinated in the public interest.

Based on these considerations, the Nuffield Council states that in 2007 in the United Kingdom, there were not enough reasons to make the routine vaccination of children mandatory or optional with incentives.

5.8. Responsibility of parents, public authority and private individuals

The parents, and where appropriate the people assuming responsibility for their children on their behalf, indisputably have a duty to protect them. This obligation arises not only from the Convention on the Rights of the Child, but also from a general ethical concept.

Although they sometimes receive contradictory information, parents have a moral duty to base their attitude to vaccination on rational considerations. In this context it is vital to realise that the usefulness and even the necessity of the vaccination of children against certain pathologies has been scientifically proven.

In effect, although many bacterial infections may be treated using antibacterial agents (antibiotics), it is recommended as indicated in the introduction to prevent bacterial infections insofar as possible by vaccination. Some infections can develop into serious illness very quickly. Moreover, the development of resistance to antibiotics is a problem that is becoming more and more frequent. Antibiotics may also lead to undesirable side effects.

In recent years, special antivirals have also been developed to combat certain viruses (such as HIV, Hepatitis C, Hepatitis B, etc.) However, these antivirals are not always effective and they have to be taken over long periods (sometimes even for life). They are usually particularly expensive as well and may cause side effects. Besides, no antiviral treatment is available for many viral infections that are likely to have serious consequences and for which an effective vaccination is available (polio, smallpox).

Public authority intervention is justified when the parents refuse to have their child vaccinated

against some particularly serious pathologies, such as polio, as the risk involves only to their own children but the possible spread of the infection to others.

Similarly, it is also acceptable for the competent public authorities - insofar as they have control over the crèches or run them themselves - or for private individuals who are authorised by law to run a crèche to limit access to children who have received specific vaccines.

It is true that children who have not been vaccinated and arrive in a place where there is a high level of vaccination only present a small risk of being contaminated, but there are not sufficient grounds for refusing to participate in the maintenance of the protection level. In fact, from an ethical viewpoint, it is not justifiable to benefit from the fruits of a system without making one's own contribution. The only accepted exceptions are cases with medical grounds.

Besides, parents of vaccinated children enrolled in the crèches are within their right to expect that all children attending the crèche have been treated in the same way.

5.9. Provisional conclusion

Although it is preferable to have voluntary vaccination, with nevertheless sufficient information for the public on the advantages and possible risks associated with certain vaccines, the public authorities may impose vaccination to prevent serious infectious diseases (such as polio) including for children.

This does not rule out the fact that the public authorities should monitor the continuous assessment of the vaccines in terms of the effectiveness and safety of the vaccines proposed in the definition of their competence, and that this should be done without any commercial influence.

6. Conclusions and recommendations

Before answering the 4 questions listed below, the members of the Committee would like to point out that a scrupulous assessment based on scientific criteria must be carried out examining the risk associated with a vaccination and comparing to the inherent risk of the disease itself.

Moreover, it is important to become acquainted with the worries felt and expressed by people who are hesitant. Healthcare professionals should be provided with the tools to allow them to cope with this and respond appropriately.

We must be able to feed the debate about the situation experienced by the people involved and follow up on the following matters:

- justification and consistency of vaccination programmes, their place alongside other public health measures, the aims being pursued and the anticipated higher standard of well-being;
- knowledge on the harmlessness of adjuvants;
- the independence of scientific referents, when they issue recommendation and
- the autonomy of the policy authorities vis-à-vis the pharmaceutical industry, given that vaccines are products put on the market for profit.

The more we give attention and importance to the worries of people, the more receptive they will be to appeals to their sense of solidarity as responsible citizens.

Question 1: Is it ethically acceptable for authorities to impose certain vaccinations?

Maintaining the vaccination coverage of a population at a certain level for the improvement of public health is a vital task for governments. They have various resources at their disposal for this mission. First, it is incumbent upon them to ensure correct organisation of the vaccination policy (accessibility, individual cost, registration etc.). The authorities can also take or support initiatives encouraging the population to get vaccinated. Vaccination statistics in our country show that this strategy has yielded very good results, at least for children, and that currently it is not necessary - nor indeed timely - to extend the legal obligation. The vaccination rate recorded for certain highly recommended vaccines is not very much lower than the rate for the mandatory polio vaccine.

The members of the Advisory Committee nevertheless consider that the authorities could impose an obligation to be vaccinated if there were serious reasons for different motives. This could be in the case of a reduction in the voluntary vaccination cover rate among certain sub-groups of the population or in the case of the emergence of real signs of a serious epidemic.

If the public authorities take the initiative of highly recommending a vaccination, even making

it mandatory, they should make provision for fair compensation for the rare cases where that vaccination causes serious undesirable effects.

Question 2: Is it ethically acceptable for authorities to refuse children who have not been vaccinated access to childcare centres?

The members of the Advisory Committee are of the opinion that motivation and encouragement to be vaccinated should outweigh the sanction of refusal of access to a crèche.

However, if there is a risk of a public health problem - due, for example, to a rate of cover that is too low against a serious disease for which a vaccination offers effective protection - the members of the Advisory Committee consider it ethically acceptable for the authorities to impose that vaccination as a condition of access to a crèche, since the benefit of the vaccination (safe enrolment of children) may be linked to the fact of being disposed to participate actively in the preservation of this system.

Question 3: Is it ethically acceptable for a person to refuse to be vaccinated?

It all depends on the vaccine, the disease and the circumstances.

One of the aims of vaccination is to protect the person in question against a given disease. In our society each person enjoys the requisite autonomy to determine for themselves if and to what extent they will have recourse to preventive medical interventions. The freedom to not be vaccinated is defensible from an ethical point of view. Moreover, this freedom has been given legal grounds through the law on patient rights. Each adult is, therefore, free to decide whether or not to have a vaccine against tetanus, for instance. In effect, only people who decide not to have the vaccine will bear the consequences.

The law restricts this freedom under specific circumstances. The vaccination against yellow fever is mandatory for some travel, and some work contracts require a vaccination against Hepatitis B. Refusal to have the vaccine in these cases is certainly ethically defensible but will have practical prejudicial consequences (impossible to travel or do a given job).

Another aim of vaccination is the protection of others, including fellow citizens who are ill, patients and the community as a whole. From an ethical viewpoint, it is very important to contribute to this objective.

After intense reflection, the authorities may make some vaccinations mandatory. Such decisions involve vaccinations against highly contagious serious diseases against which vaccination offers effective protection, for example polio (See reply to the first question). The members of the Advisory Committee consider compliance with this obligation as a legally binding obligation for each citizen but also an ethical obligation with a view to protecting

one's fellow citizens, one which exists even without a legal obligation.

The same reasoning could be applied to optional vaccinations which have the aim of protecting others. Members of the Advisory Committee find it hard to understand and ethically disconcerting that only a limited fraction of care staff working in hospitals and other care centres have the flu vaccination every year.

Question 4: Is it ethically acceptable for a parent to refuse to have their child vaccinated?

Once again, it all depends on the vaccine, the disease and the circumstances.

It is ethically unacceptable for a parent to deprive their child of an effective vaccine against a serious and avoidable disease such as polio and tetanus. On the other hand, it is ethically acceptable for a parent to refuse to have their child vaccinated when the report on vaccination/disease risks is not scientifically decisive.

Parents must always make their decisions in the interest of the child and it is not legally or ethically acceptable for them to make decisions that are clearly harmful for their child.

With regard to the protection of others, the reply to Question 3 above holds true.

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This opinion was prepared by select commission 2012-3bis consisting of:

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The working documents of the select commission – the question, personal contributions of the members, minutes of the meetings and documents consulted – are kept on file at the Committee's documentation Centre where they are available to be consulted and copied.

This opinion is available to be consulted at www.health.belgium.be/bioeth

Annexe à l'avis n°64 du 14 décembre 2015

[Annex not translated]

Législation et réglementation des Communautés

1. Communauté flamande

1.1. Décret du 1er décembre 1998 relatif aux centres d'encadrement des élèves

(M.B. du 10 avril 1999)

Article 18. « Le centre prend des initiatives tendant à stimuler, à contrôler et à sauvegarder la santé, la croissance et le développement des élèves. En plus du fonctionnement multidisciplinaire, cela implique :

1°[…];
2° *que le centre prend, à l'égard des élèves, des mesures pour éviter que certaines maladies contagieuses surgissent. Le Gouvernement définit les mesures à prendre et fixe le schéma de vaccination*;
3° que le centre prend, à l'égard des élèves et du personnel scolaire, des mesures prophylactiques pour éviter que des maladies contagieuses se répandent. Le Gouvernement en fixe les modalités. » (nos italiques)

1.2. Décret flamand du 21 novembre 2003 relatif à la politique de santé préventive

(*M.B.* du 3 février 2004)

Article 8. « Dans le cadre du champ d'application du présent décret, toute personne a une responsabilité individuelle par rapport à sa propre santé et, par les actes qu'elle pose ou manque de poser volontairement et consciemment, *également par rapport à la santé de son prochain*. Cette responsabilité comprend la prise en considération des prescriptions de sécurité, l'adoption d'un style de vie sain et la prise *d'autres mesures de précaution réalisables et efficaces dans le but de prévenir des maladies et affections chez l'homme*. » (Nos italiques).

Article 11. « Toute personne a *l'obligation de se soumettre à une intervention de soins de santé préventifs qui est nécessaire pour ne pas mettre en danger la santé d'autres personnes* […], lorsqu'elle :
1° se trouve sur le territoire de la Région flamande et cette intervention en Région flamande

est fournie par une organisation partenaire, une organisation œuvrant sur le terrain ou un prestataire de soins individuel;
2° a) se trouve sur le territoire de la Région bilingue de Bruxelles-Capitale et cette intervention en Région bilingue de Bruxelles-Capitale est fournie par une structure qui, de par son organisation, doit être considérée comme relevant exclusivement de la compétence de la Communauté flamande et pour autant qu'elle a volontairement fait appel à cette structure;
b) se trouve sur le territoire de la Région bilingue de Bruxelles-Capitale et cette intervention en Région bilingue de Bruxelles-Capitale est fournie par un prestataire de soins individuel qui s'est affilié volontairement à un groupement qui est organisé lui-même de telle façon qu'il témoigne d'un lien avec la Communauté flamande et pour autant que la personne a volontairement fait appel à ce prestataire de soins individuel. » (Nos italiques).

Article 43. « § 1. En vue de prévenir certaines infections, le Gouvernement flamand établit un schéma de vaccination qui reprend les vaccinations recommandées pour la population, et il informe les vaccinateurs et la population à ce sujet.
§ 2. Le Gouvernement flamand prend des initiatives visant à atteindre un taux de vaccination aussi élevé que possible de la population.
§ 3. Les vaccinateurs doivent collaborer à un système d'enregistrement à déterminer par le Gouvernement flamand.
§ 4. Le Gouvernement flamand peut fixer les circonstances dans lesquelles des vaccins ou des moments de vaccination sont recommandés autres que ceux repris dans le schéma de vaccination visé au § 1er. »

1.3. Décret du 30 avril 2004 portant création de l'agence autonomisée interne dotée de la personnalité juridique "Kind en Gezin" (Enfance et Famille)
(*M.B.* du 7 juin 2004)

Article 7. « § 1. La tâche de l'agence relative à l'organisation du soutien aux familles préventif comprend en tout cas :
1° l'information et la fourniture de services de conseil aux familles et aux futurs parents concernant la santé, le développement, l'éducation, la nourriture et la sécurité des enfants;
2° le suivi, la détection et la signalisation de risques concernant la santé, le développement et l'éducation des enfants, dont la détection des cas d'enfants maltraités et l'examen de l'ouïe et de la vue;
3° *les soins de santé préventifs concernant le jeune enfant, notamment la promotion, l'administration et le suivi des vaccinations;*
4° le soutien des familles et futurs parents ayant des besoins spécifiques en matière de santé, de développement et d'éducation, dont pleurer, dormir, manger et interaction parents-enfants. » (nos italiques)

[…]

1.4. Arrêté du Gouvernement flamand du 3 juillet 2009 fixant les objectifs opérationnels des Centres d'Encadrement des Elèves

(*M.B.* du 3 juillet 2009)

« CHAPITRE V. - Vaccinations et mesures prophylactiques

Section Ire. - Dispositions générales

Article 41. L'offre de soins de santé préventifs entretient un lien avec les objectifs stratégiques visés à l'article 18 du décret du 1er décembre 1998 relatif aux centres d'encadrement des élèves.

Section II. – Vaccinations

Article 42. Afin d'éviter l'apparition de certaines maladies contagieuses, le centre assure le suivi du dossier de vaccination de tous les élèves qu'il encadre. Le ministre flamand ayant la politique de la santé dans ses attributions établit le schéma de vaccination, visé à l'article 1er de l'arrêté du Gouvernement flamand du 18 mars 2011 portant exécution de l'article 43, § 1er, du décret du 21 novembre 2003 relatif à la politique de santé préventive et modifiant l'arrêté du Gouvernement flamand du 3 juillet 2009 fixant les objectifs opérationnels des centres d'encadrement des élèves, en ce qui concerne la détermination des mesures prophylactiques, servant de fil conducteur et fixe les années d'études durant lesquelles ces vaccinations doivent être administrées. Cela est réalisé après concertation avec les réseaux du centre.

Article 43. Le centre offre les vaccinations portées dans le schéma de vaccination et vérifie le dossier de vaccination des élèves encadrés à l'occasion d'une consultation générale ou dirigée. Les concernés sont informés par écrit de la nature et des buts de la vaccination. Le centre administre les vaccinations à condition qu'il en ait reçu le consentement écrit.

Article 44. Aux élèves dont le dossier de vaccination ne répond pas au schéma de vaccination établi, le centre offre des vaccinations, éventuellement à d'autres moments que les années d'études visées à l'article 42.

Article 45. Le centre s'efforce d'atteindre un degré de vaccination d'au moins 95 % chez les élèves qu'il encadre, en vue de réaliser l'extermination totale de certaines maladies contagieuses. »

Contrairement à son homologue francophone (voir ci-dessous), Kind en Gezin *n'impose aucune vaccination pour les enfants de moins de six ans en milieu d'accueil, bien qu'il le recommande vivement.*[35]

2. Communauté française

2.1. Décret du 20 décembre 2001 relatif à la promotion de la santé à l'école

(*M.B.* du 17 janvier 2002)

Article 2. « La promotion de la santé à l'école consiste en :
1°[…];
2° le suivi médical des élèves, qui comprend les bilans de santé individuels et la politique de vaccination, tel que précisé à l'article 6 ».

Article 6. § 1. « *Les bilans obligatoires de santé individuels des élèves qui comprennent l'examen médical et son suivi ainsi que la politique de vaccination* sont réalisés, sous la responsabilité du médecin, selon les fréquences et les modalités fixées par le Gouvernement, sur avis de la Commission visée au chapitre IV.
Ces fréquences sont fixées à cinq bilans au minimum et huit au maximum sur l'ensemble de la scolarité visée à l'article 3, alinéa 1er. »
§ 2. « Le Gouvernement prévoit des modalités particulières permettant l'organisation de bilans de santé supplémentaires spécifiques pour des risques particuliers ou imprévisibles, ou pour renforcer l'égalité des chances en santé. »
§ 3. « Le Gouvernement fixe la mise en œuvre de la politique vaccinale, en déterminant les types de vaccins proposés gratuitement aux élèves, et l'âge de l'élève ou l'année scolaire auquel ce vaccin est proposé. » (nos italiques)

2.2. Décret du 17 juillet 2002 portant réforme de l'Office de la Naissance et de l'Enfance, en abrégé « O.N.E. »

(*M.B.* du 2 août 2002)

Article 6. « § 1. Nul étranger au milieu familial de vie de l'enfant ne peut organiser l'accueil d'enfants de moins de douze ans de manière régulière sans le déclarer préalablement à l'Office et sans se conformer à un code de qualité de l'accueil arrêté par le Gouvernement après avis de l'Office.
[…]
§ 2. Nul étranger au milieu familial de vie de l'enfant ne peut accueillir, sauf de manière

[35] Mouton, A., "L'obligation vaccinale : quelques enjeux du débat" (Mandatory vaccination: some issues of the debate), *o.c* ., p. 29.

occasionnelle, des enfants âgés de moins de six ans sans en avoir obtenu l'autorisation préalable de l'Office sur la base des critères qu'il prévoit, tels qu'approuvés par le Gouvernement. »
[…]

2.3. Arrêté du Gouvernement de la Communauté française du 27 février 2003 portant réglementation générale des milieux d'accueil

(*M.B.* du 21 mai 2003)

Article 2. « Les milieux d'accueil sont :
1° "la crèche" : milieu d'accueil conçu pour accueillir en collectivité et en externat des enfants âgés de zéro à trente-six mois avec du personnel qualifié et dont l'accès ne peut être limité à une tranche d'âge plus restreinte;
2° "le prégardiennat" : milieu d'accueil conçu pour accueillir en collectivité et en externat des enfants âgés de dix-huit à trente-six mois avec du personnel qualifié et dont l'accès ne peut être limité à une tranche d'âge plus restreinte;
3° "la maison communale d'accueil de l'enfance" : milieu d'accueil conçu pour accueillir en collectivité et en externat des enfants âgés de zéro à six ans avec du personnel qualifié;
4° "la maison d'enfants" : milieu d'accueil conçu pour accueillir en collectivité et principalement en externat des enfants âgés de zéro à six ans;
5° "la crèche parentale" : milieu d'accueil conçu pour accueillir en collectivité et en externat des enfants de zéro à trente-six mois encadré en partie par du personnel qualifié et en partie par des parents;
6° "le service d'accueillant(e)s d'enfants conventionné(e)s" : service chargé d'organiser l'accueil des enfants âgés de zéro à six ans chez des accueillant(e)s d'enfants conventionné(e)s auprès dudit service. Ce service peut être une crèche ou une maison communale d'accueil de l'enfance;
7° "l'accueillant(e) d'enfants" : personne physique qui assure un accueil à caractère familial pour des enfants de zéro à six ans dans un lieu adapté à cette fin et qui est soit conventionné(e) avec un service visé au 6°, soit autonome. Deux accueillant(e)s conventionné(e)s au plus ou deux accueillant(e)s autonomes au plus peuvent exercer leur activité ensemble en un même lieu;
8° tout autre milieu d'accueil organisant l'accueil d'enfants âgés de zéro à six ans de manière régulière sous une autre forme que celles visées ci-dessus, pour autant que celui-ci ne soit pas exclu par l'article 6, § 3, du décret. »

[…]

Article 17. « Le milieu d'accueil rédige un règlement d'ordre intérieur selon le modèle type

recommandé par l'Office, précisant les droits et obligations réciproques des parents et du milieu d'accueil.
Ce règlement d'ordre intérieur est soumis à l'approbation de l'Office qui vérifie sa conformité avec la réglementation. *Il est signé pour accord par les parents au moment de l'inscription de l'enfant.* » (nos italiques)

[…]

Article 31. « Sauf décision médicale, laquelle est sur la demande du milieu d'accueil confirmée par le conseiller médical de la sub-région*, tout enfant est vacciné* selon les modalités déterminées par l'Office dans le cadre du schéma élaboré par la Communauté française. Les vaccinations sont pratiquées par le médecin de la consultation des nourrissons ou par un médecin choisi par les parents. Dans ce cas, les parents fournissent au milieu d'accueil la preuve des vaccinations. « (nos italiques)

2.4. Modèle de Règlement d'ordre intérieur basé sur l'article 17 de l'arrêté du Gouvernement du 27 février 2003 (version du 11 octobre 2004)[36]

I.J. Surveillance médicale

Vaccination

« Les parents s'engagent à faire vacciner leur enfant ou à donner l'autorisation au médecin de la consultation pour enfants de l'O.N.E. de pratiquer les vaccinations, selon le schéma que l'Office préconise conformément à celui élaboré par la Communauté française. »

« Les enfants doivent obligatoirement être vaccinés contre les maladies suivantes :
- Diphtérie – Coqueluche – Polio ;
- Haemophilus influenza b ;
- Rougeole ;
- Rubéole ;
- Oreillons.

Quant aux autres vaccins recommandés par la Communauté française, ceux-ci le sont d'autant plus vivement lorsque l'enfant est confié à un milieu d'accueil. » (nos italiques)

« Toutefois, si le médecin de l'enfant estime un vaccin préconisé par l'O.N.E. inopportun pour des raisons médicales propres à l'enfant, il en fait mention ; le dossier sera ensuite examiné

[36] http://www.vaccination-info.be/questions-reponses/questions-generales/99-vacciner-son-enfant-est-il-obligatoire-dans-un-milieu-d'-accueil

par le médecin de la consultation et le conseiller médical pédiatre de l'O.N.E., afin de déterminer si l'enfant peut ou non continuer à fréquenter la structure d'accueil. »

2.5. Annexe à l'arrêté du Gouvernement de la Communauté française du 14 juillet 2011 relatif aux mesures de prévention des maladies transmissibles dans le milieu scolaire et étudiant

(*M.B.* du 20 septembre 2011)

[Trois maladies relèvent de l'urgence sanitaire : les méningococcies, la diphtérie, la poliomyélite.]

« 1. Méningococcies

[…]
Une vaccination, adaptée au sérotype, des personnes ayant présenté des contacts à haut risque est recommandée lorsque surviennent 2 cas dans l'école sur une période d'un mois.
[…]

2. Diphtérie

[…]
Rappel de vaccination pour les élèves dont le dernier rappel remonte à plus de deux ans.
Vaccination des élèves/étudiants non vaccinés, selon le schéma en vigueur.
(nos italiques)
[…]

5. Hépatite A

[…]
b) Lorsque 2 cas non familialement apparentés surviennent dans un délai d'un mois dans une même classe, la vaccination est recommandée à tous les élèves/étudiants de la classe. La vaccination est également recommandée à tous les élèves/étudiants de l'enseignement spécial ou des internats qui ont présenté des contacts rapprochés avec le malade. […]
c) Dès la survenue du premier cas, les élèves/étudiants et leurs parents seront informés quant aux modes de transmission de la maladie et aux possibilités de vaccination.

[…]

8. Coqueluche

[…]
b) Chez les élèves d'une classe de l'enseignement maternel ou primaire qui présentent une couverture vaccinale incomplète ou inexistante, une antibioprophylaxie et une vaccination seront recommandées. *En cas de refus de la seule vaccination, l'élève/étudiant sera évincé de l'école pour une période de 5 jours*, pour autant que l'antibioprophylaxie lui ait été correctement administrée. *En cas de refus, tant de la vaccination que de l'antibioprophylaxie, l'élève/ étudiant sera évincé 21 jours*.
Chez les élèves/étudiants de la classe en âge de fréquenter l'enseignement secondaire et au-delà, seule la vaccination sera recommandée, en cas de couverture vaccinale incomplète ou inexistante. L'antibioprophylaxie systématique ne sera pas recommandée.
Aucune mesure prophylactique particulière ne sera appliquée chez les élèves/étudiants en ordre de vaccination. » (nos italiques)
[…]

9. Oreillons

[…]
b) La vaccination par le vaccin trivalent « Rougeole-Rubéole-Oreillons » sera recommandée aux élèves/étudiants de la classe dont l'historique vaccinal serait incomplet ou inexistant.
[…]

10. Rougeole

[…]
b) La vaccination par le vaccin trivalent « Rougeole-Rubéole-Oreillons » sera recommandée aux élèves/étudiants de la classe dont l'historique vaccinal serait incomplet ou inexistant. Elle sera administrée endéans les 72 heures à partir de la survenue du cas index. Un rappel de vaccination est particulièrement recommandé chez les personnes nées après 1975.
[…]

11. Rubéole

[…]
b) La vaccination par le vaccin trivalent « Rougeole-Rubéole-Oreillons » sera recommandée aux élèves/étudiants de la classe dont l'historique vaccinal serait incomplet ou inexistant. »
[…]

3. Communauté germanophone

L'accueil de la petite enfance a fait l'objet d'une nouvelle réglementation. Il s'agit du décret du 31 mars 2014 relatif à l'accueil d'enfant (*M.B.* du 2 juillet 2014) et l'arrêté du 22 mai 2014 relatif aux services et autres formes d'accueil d'enfants (*M.B.* du 24 septembre 2014 Ed.2). C'est ainsi que actuellement la question de la vaccination est réglée par l'article 89 de l'arrêté du 22 mai 2014 qui renvoie aux articles 67-69 (accueillantes). L'article 68 prévoit uniquement que le service d'accueil d'enfants conseille de faire vacciner les enfants gardés par une accueillante. Le ministre de la Santé publique A. Antoniadis a demandé de préparer une modification de l'arrêté du 22 mai 2014 afin d'inscrire l'obligation de vacciner les enfants accueillit en crèche.

4. Région de Bruxelles-Capitale

Une ordonnance relative à la politique de prévention en santé a été prise le 19 juillet 2007 (*M.B.* du 24 août 2007) et un arrêté du Collège réuni de la Commission communautaire commune du 23 avril 2009 (*M.B.* du 18 juin 2009) en exécute les mesures relatives aux maladies transmissibles. De manière générale l'article 10 de cette ordonnance habilite le Collège réuni à prendre des initiatives visant à dépister, prévenir ou limiter les dommages à la santé causés par des maladies et des affections.

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