

JOINT REPORT ON

Protecting the population against infectious diseases



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Introductory word

The Supreme Audit Institutions of Belarus, Hungary, Poland, and Slovakia have carried out an international audit resulting in a present report. The joint work focused on states' activities related to the procedure for epidemiological emergencies and on compulsory vaccination.

The subject topic was the result of an analysis of the public health situation as early as 2019. Cooperation was declared a few months before the COVID-19 outbreak. The content of the audit has been agreed in such a way that the results can be analysed and compared, highlighting best practices, as well as issues that have arisen in solving the problem.

Mutual cooperation, assistance and coordinated efforts are a way of achieving the desired objective. This audit also points to the fact that mutual communication, by comparison, shows us new ways that can be used to solve problems.

1. Summary and evaluation of the results of control activities

Infectious diseases have not been an atypical phenomenon during the evolution of mankind, they have accompanied us for centuries, not infrequently with a high mortality rate. It was only the discovery of vaccination, which is now an important and effective method of prevention, which turned around the situation. Its effectiveness is proven by the decline or disappearance of diseases that can be prevented thanks to vaccination. However, even today, the intensive movement of the population around the world does not preclude the introduction of infectious diseases into any country. Therefore, the WHO **recommends that we reach a certain level of vaccination** that will ensure the **collective immunity** of the population.

What has been happening in recent years shows us how topical the chosen area of compulsory vaccination is. This knowledge was the basis of the Supreme Audit Institutions of Belarus, Hungary, Poland, and Slovakia when they first attended a working meeting on the subject in November 2019. The negotiations resulted in an agreement on the implementation of the joint audit. Each of the participating countries proceeded to carry it out in its own way, controlling different entities, also adapting the contents to its needs.

When assessing the results of audit, it is worth pointing out a common past, similar ways of addressing health policy in the field of prevention and organizing the compulsory vaccination process in Central and Eastern Europe during the second half of the 20th century. Some of the learned and tried-and-tested procedures have persisted to the present, some have been modified or changed, but the importance of vaccination and the associated willingness of the population to get vaccinated are, at least for the most part, still present in society.

The **audit focused** on the preparedness of countries to deal with epidemiological emergencies (as an initial response to the situation regarding COVID-19, which broke out in the process of preparation of the international audit), on the provision of collective protection of the population and the measures taken in the context of the decline in compulsory vaccination coverage, as well as on the availability of vaccines for compulsory vaccination. The purpose of the audit was to assess whether the population is sufficiently protected against infectious diseases.

The theoretical preparation of procedures for epidemiological emergencies in individual countries was based on assumptions, like any other theory. The evolution of epidemiological emergencies is difficult to predict. Assessing which of the steps to take at a given moment is an extremely responsible decision, the success of which we can hardly estimate.

The situation resulting from COVID-19 has long been unknown to our geographical area, which was evident in this audit (despite assessing only the initial phase of the pandemic).

Hungary only assessed in the audit the existence of procedures for epidemiological emergencies, while Poland and Slovakia also looked at their use in the early stages of the pandemic.

In Poland state of epidemic was introduced in March 2020; while none of the „extraordinary states“ laid down in the Polish Constitution were proclaimed; in Slovakia, an emergency situation was declared almost immediately, and later higher level – major emergency was declared. In addition to the legislatively anchored forces responsible for dealing with epidemic emergencies, the governments have also created new bodies.

Developments have forced the responsible authorities of both States to adapt existing rules and regulations. The restrictions and prohibitions issued by the competent authorities have been **called into question** in terms of respect for constitutional rights and became subject of actions. Further development of the situation was no longer included in this audit action, so the solution will bring the future.

Another area considered was organization of the systems of compulsory vaccinations against infectious diseases and achievement of collective immunity of the population for compulsorily vaccinated diseases and the procedures applied by States when vaccination coverage levels have declined.

During the period covered by the audit, vaccinations were **compulsory** in Hungary, Poland, and Slovakia during the audited period, and was on a voluntary basis in Belarus.

The procedures for compulsory vaccination were similar. The audit compared the range of diseases vaccinated against in each country, as well as how the population's immunity status against communicable diseases is assessed (the so-called immunological overview). Based on the results of the immunological overview, the vaccination calendar subsequently changed. Its implementation took place differently. In Belarus, a coefficient was established considering vaccination coverage and data on the number of persons with protective antibody titres after vaccination and in the unvaccinated group. In Poland, they analysed data on vaccination coverage of a given year and the previous period, in Slovakia based on examination of blood samples, from which the sufficiency of the formation of antibody levels against the diseases studied was determined.

The way vaccination data were recorded was also different. Centralised registers of vaccinated persons have been in Hungary and Poland, in Belarus partial registers in individual health organisations. In Slovakia, the data were summarised as part of the administrative control of compulsory vaccination. An online register is currently being prepared containing real-time vaccination data.

The audit found that, in period covered by the audit, in general, vaccination outcomes were achieved in the audited period, which guaranteed a sufficient level of collective immunity. Lower values were only for mumps/rubella/measles vaccination in Poland in 2017-2019 and in Slovakia in the period 2015-2017. The result of just under 95% was recorded in Poland in 2019 for pneumococci, whooping cough, polio, and haemophilic diseases.

As vaccination rates declined, States appealed to the importance and significance of vaccination. They carried out educational activities, organized lectures, issued guidelines and recommendations, communicated via social media. For those refusing vaccinations, States had procedures in place and worked with opposing groups. Even fines were imposed in Poland, and Slovakia for refusing vaccination. In Slovakia, audit pointed to inconsistent regional rules when imposing them. The Polish audit found that primary care physicians did not report cases of avoidance of vaccination, and district sanitary and epidemiological stations staff made no recommendations on the problem despite frequent inspections at primary care facilities. They also identified this issue as a potential topic for the next audit.

Despite a number of **support activities, their sufficiency** is questionable, especially in the current situation, when the activities of anti-vaccination movements are on the rise. Moreover, the effectiveness of the activities carried out has not been quantified, so we cannot assess their success in terms of interest in vaccination.

Finally, the availability and method of obtaining vaccines was the area that was compared. Belarus, Hungary and Poland procured vaccines in a centralised manner through public procurement. In Slovakia, since 2005, the method has been decentralised, vaccines have been categorized in the same way as other medicines, ordered by pharmacies based on orders from vaccinating doctors. The centralised method was based on consumption planning, which is particularly important for vaccines whose manufacturing and technological processes differ from conventional medicines.

A national audit by the Supreme Audit Office of the Slovak Republic pointed to the fact that in the decentralised method there were vaccine shortages, there was no information about their availability. It noted that in order to solve the problems of their availability it is necessary **to seek solutions and systemic measures** to eliminate the undesirable situation.

The WHO estimates that compulsory vaccination saves between 2 and 3 million lives a year. Consistent implementation of the immunisation programme also saves funds, thanks to a well-set vaccination programme, the population needs fewer medicines and fewer hospitalizations. In the context of the increasing risk of introduction of communicable diseases that do not respect borders or other barriers, due attention must be paid on a daily basis to protecting the population from infectious diseases, improving procedures, educating and appealing to the responsibility of all of us towards ourselves and others.

2. Introduction

a. Characteristics of the subject and purpose of control activities

The issue of protecting the population from infectious diseases has resonated in society for a longer time, with a view to awareness of the increased risk of developing and spreading communicable diseases, extensive international travel and trade, legal and illegal migration.

At the end of 2019, representatives of the Supreme Audit Institutions of **Belarus, Hungary, Poland, and Slovakia** agreed to conduct an audit that was primarily focused on this area. In response to the emerging situation regarding the COVID-19 pandemic, at the beginning of 2020, the common interest was extended to include the review of procedures and preparedness for dealing with epidemiological emergencies.

The initiator and the coordinator of the international audit was the Supreme Audit Office of the Slovak Republic. The joint agreement showed that the audit would focus on procedures to ensure preventive measures in the event of epidemiological emergencies, ensure collective protection of the population, the effectiveness of measures to prevent a decline in compulsory vaccination coverage and the availability of vaccines.

The institutions involved aimed to ensure that individual national audits were targeted in a way that would allow analysis, mutual comparison and evaluation of the facts established.

b. Definition of cooperation between Parties

The national working teams have reached a common consensus on the content and form of the audit. They agreed on the common audit questions to be answered by the audit and on the timetable for the audit. In August 2020, bilateral cooperation agreements were signed between the Supreme Audit Office of the Slovak Republic and each of the other participating Supreme Audit Institutions.

Based on the agreement, the Belarusian side did not address the issue of epidemiological emergencies.

The exchange of interim results took the form of videoconferencing, any joint meetings did not take place due to the COVID-19 epidemic. For the same reason, the timeframe for conducting national audits and, consequently, for drawing up a joint final report has been postponed.

The results of coordinated national audits form the content of this mutually agreed joint final report, which may be provided to selected national and foreign institutions. It may also be published on the websites of the participating SAIs. The report provides information on the period 2015-2020.

3. Procedures to ensure preventive measures in the event of epidemiological emergencies

a. Legal regulation of the procedures for the extraordinary epidemiological events

Preparedness for dealing with epidemics is one of the basic conditions for successfully stopping their spread. A communicable disease outbreak is referred to as an epidemiological emergency, which is the occurrence of a communicable disease or suspected communicable disease, as well as a death above the expected level in a given place and time.

Clear and well-defined procedures are key to preparedness **to cope with epidemiological emergency**. The participating countries have dealt with the issues in diverse ways by adapting procedures in this area.

In Hungary, the Ministry of Human Resources was responsible for this area. During the period under review, there were guidelines and procedures for maintaining the vaccination system, strengthening epidemiological safety, and modernising it. In 2011, the Semmelweis Plan was adopted, which was an assessment of the health condition of the Hungarian population and proposed measures to maintain a healthy environment and epidemiological safety. To achieve this, the health sector strategy "Healthy Hungary 2014-2020" was adopted and subsequently fulfilled by a government decision. The audit found that the strategic planning documents prepared by the Ministry of Human Resources for 2019 did not contain any guidelines and procedures for the management impact of population movements and climate change on human health and the spread of communicable diseases. However, the solution was the subject of Action Plans subsequently adopted. The Ministry of Human Resources has also approved sub-plans for the health crisis management plans prepared by government authorities.

The activities of the authorities in Poland related to prevention and preparedness for emergencies were regulated by law and planned in the National Emergency Management Plan. It also included epidemiological emergencies. In the case of an epidemiological emergency, the Minister of Health and the Chief Sanitary Inspector were responsible for the action. Emergency management plans were developed at all administrative levels. The plans at the regional level included information on the resources needed and the phasing of the deployment of health facilities and hospitals identified as potential centres for the treatment of infectious diseases.

During the period covered by audit, in the event of crises, the crisis management bodies in Slovakia dealt with the management of the processes during the audited period. During epidemiological emergencies, the Public Health Authority of the Slovak Republic entered into this process, which was responsible for the prevention and control of communicable diseases. The National Anti-Epidemic Commission under the authority of the Office performed tasks in the event of public health threats related to the emergence of an epidemic, other massively occurring communicable diseases of widespread importance, or the risk of their emergence.

An important document related to the protection of the population from infectious diseases in SR was the National Infectious Disease Control Plan - a strategic plan for the fulfilment of tasks in the form of action plans to improve results in the field of infectious disease control. Responsibility for the implementation of individual strategies in the years 2019 – 2020 was broad-based, in addition to the Ministry of Health and the Public Health Authority of the Slovak Republic, other bodies, companies and associations were involved. The action plans focused, among other things, on a functional network of national databases for data collection and analysis, on the National Immunisation Programme of the Slovak Republic and on epidemiological workplaces for the prevention and control

of communicable diseases. Following the COVID-19 outbreak, the implementation of the National Plan has been suspended, the tasks are not completed, they are at various stages of development.

b. Solution of extraordinary epidemiological events in the current period and in an emergency – comparing and identifying differences

The occurrence of communicable diseases in general and epidemics can be prevented, but they cannot always be avoided. It is therefore necessary for the State to have defined responsible actors for dealing with epidemic emergencies, who can act without hesitation when necessary.

The audit revealed that each of the participating countries **had bodies set up during the period under review** and their responsibilities and powers were clearly defined.

In Hungary, such a unit existed until 30 September 2018 within the Ministry of Human Resources. Subsequently, a National Public Health Centre was established. The audit showed that since the date of its establishment it operated for about 7 months without organisational and operational rules, only based on temporary operating rules issued by the National Chief Medical Officer.

In Poland, a Government Emergency Management Team and a Government Safety Centre operated under emergency management plans. In addition, during the COVID-19 pandemic, the Prime Minister used the experience of national consultants and in November 2020 set up a medical council composed of experts dealing with epidemics. The Minister of Health and the Chief Sanitary Inspector have also set up specialised teams and working groups. The NIK's audit described the activities of these units and concluded that in crisis situations the institutions, structures and procedures described in emergency management plans should have been used first. Thematic teams, working groups, etc., can be useful as supporting elements, but compliance with the rules applicable in emergency situations is the responsibility of public authorities.

An analogous situation was found in Slovakia. In the event of epidemiological emergencies, the Central Crisis Staff established by the Slovak Government, the Pandemic Commission of the Slovak Government and the National Anti-Epidemic Commission are active. In addition, during the first wave of the COVID-19 pandemic (March 2020), a temporary advisory and coordinating body to the Prime Minister – Permanent Crisis Staff was established.

Until July 2020, the Pandemic Commission of the Slovak Government had only the handling of influenza pandemics in its scope, but now the statute has been modified and the Commission acts in the event of any pandemic. In August 2020 it approved a Pandemic Plan for a pandemic in the Slovak Republic, until then the Slovak Republic had no such plan.

• COVID-19 pandemic period

Only the Supreme Audit Institutions of Poland and the Slovak Republic dealt in their reports in more detail with the conduct during the first year of the COVID-19 pandemic in their reports.

The World Health Organization has declared a pandemic of COVID-19 on 11 March 2020. In the case of both countries, it can be noted that the authorities responsible for controlling the spread of infectious diseases **responded to the pandemic in a timely manner and took the necessary measures.**

On the day, the pandemic was declared, the Public Health Office of the Slovak Republic, which carries out prevention and control of communicable diseases, proposed to the Government of the Slovak Republic to declare an emergency situation in the territory of the Slovak Republic (the Government accepted the proposal). At the same time, it proposed to adopt specific tasks and measures aimed at saving life, health and property, to take measures

to reduce the risks of danger, and to determine the procedures and activities for dealing with the consequences of the communicable disease.

In Poland, the state of epidemic was declared, while none of the “extraordinary states” provided for in the Polish Constitution had been introduced, therefore all actions of the public authorities were to be based on existing legislation.

The new, unknown situation and its constant evolution have brought with it **the need to adapt existing rules and regulations**. While in Slovakia the Public Health Authority issued measures, in Poland their issue was the responsibility of the Council of Ministers and the Minister of Health. In addition, in Poland, the Chief Sanitary Inspector also issued guidelines, recommendations and notices on COVID-19. These regulations provided for various restrictions and prohibitions in both countries (border area, holding mass events, wearing masks, visits to health and social care facilities, etc.), as well as guidelines for primary care physicians, outpatient specialists, rehabilitation centres, etc. The frequency of changes was extremely high, 105 measures were issued in Slovakia by the end of January 2021, in Poland by the end of August 2021 the Council of Ministers and the Minister of Health issued 75 implementing regulations, the Chief Sanitary Inspector drew up 195 guidelines between March 2020 and March 2021. Such **frequent changes** have been shown to lead to some fatigue and apathy even with an effective information policy, thus make compliance more difficult.

The development of the situation in Slovakia revealed shortcomings in the law based on which the regulations were issued, the competences of the Public Health Authority of the Slovak Republic were questioned when they were issued in certain situations. In October 2020, the law was amended. Because of this questioning, the Public Health Authority of the Slovak Republic faced lawsuits that challenged the legality of the intervention of a public authority (through the issuing of measures).

Poland has also tackled the problem of challenging the restrictions adopted, in several cases the courts have annulled fines imposed for breaching the restrictions.

In November 2020, eight months after the pandemic began, a 'One Hundred Days of Solidarity' action plan was adopted in Poland to combat COVID-19. It presented criteria for the introduction and lifting of epidemic-related restrictions depending on the dynamics of the infection. It consisted of three stages, the last stage being a national quarantine. This was to be introduced from December 28, 2020, even though the average number of cases per seven days set out in the Action Plan has not been reached. In fact, the rules of the Action Plan worked for four weeks, followed by the renewed previous system of ad hoc public announcements on the introduction of new rules.

• **Monitoring of the situation related to epidemiological emergencies**

Monitoring and coordination of procedures are particularly necessary for the spread of diseases. Monitoring of the epidemiological situation is based on the continuous reporting of communicable diseases by health professionals who are legally obliged to report status of these diseases.

In Europe, the following systems to monitor infectious diseases are used, each focusing on one area:

- EWRS (Early Warning and Response System) - threat detection, threat warnings,
- EPIS - epidemiological reporting
- TESSy – disease surveillance and statistics.

The audit revealed that the epidemiological situation was monitored during the period under review. In Hungary, the department of the Ministry of Human Resources performed this task until 30 September 2018, after which it was taken over by the National Public Health Centre. In Poland it was the Chief Sanitary Inspectorate and in Slovakia the Public Health Authority.

4. Assurance of the collective protection of the population

Individual States are responsible for their public health strategy. Public health strategy highlights risks to human health and seeks to prevent these risks.

Individuals also prevent risk of infectious diseases by building immunity. Immunity is the defensive capacity of our body against dangerous influences of the surrounding environment. While individual immunity (obtained by recovering from the disease or by vaccination) protects the individual, collective immunity prevents the further spread of infection and is a prevention against epidemics or pandemics. Collective immunity depends on millions of responsible individual decisions. The more people in the general population are vaccinated against a certain causative agent of the disease, the greater the chance of limiting the spread of the disease.

a. Legal regulation of ensuring the vaccination of the population

During the period covered by the audit, the system of ensuring the vaccination coverage of the population was modified in several ways during the audited period. In Belarus, it was the Ministry of Health, in Hungary the National Public Health Centre (until 30 September 2018 the Ministry of Human Resources), the National Sanitary Inspection in Poland and the Public Health Authority in Slovakia were responsible for planning, coordinating and supervising vaccination.

Vaccination has been **adequately legislated for** in all countries. Vaccination against most of the infectious diseases is compulsory in Hungary, Poland and Slovakia – according to the vaccination calendars, in Belarus it is voluntary.

There were differences between countries in national approach to the implementation of the national immunisation programme and differences in vaccination calendars (in the range of diseases, in the specification of the vaccinated population, e.g., only for at-risk groups, at the age when vaccination takes place, in the exact type of vaccine, in the vaccination interval, etc.).

The list of diseases against which it is compulsory to vaccinate has been reflected in the annual vaccination calendar. The calendar was the result of factors such as disease burdens, disease prevalence and country trends, political and cultural factors, the robustness of vaccination programmes.

In the countries involved in the audit, the following diseases are compulsorily vaccinated:

Table 1: Compulsory vaccination in individual countries

Disease	Belarus	Hungary	Poland	Slovakia
Diphtheria	✓	✓	✓	✓
Tetanus	✓	✓	✓	✓
Pertussis	✓	✓	✓	✓
Portable polio	✓	✓	✓	✓
Hepatitis type B	✓	✓	✓	✓
Invasive haemophilic diseases	✓	✓	✓	✓
Pneumococcal invasive diseases	✓*	✓	✓	✓
Measles	✓	✓	✓	✓
Mumps	✓	✓	✓	✓
Rubella	✓	✓	✓	✓
Tuberculosis	✓	✓	✓	✗
Influenza	✓*	✗	✗	✗
Chickenpox	✗	✓**	✓*	✗

Source: National Reports

* Only at-risk groups

**Compulsory for children born after 31.07.2018

The way vaccination was organised was the same across countries. Vaccination was conducted by first-contact physicians, whose duty was to notify the person concerned or his or her legal representative in writing of the obligation to vaccinate. Once the date had been set and the vaccination had been administered, this information was recorded in the medical records.

A Vaccination Register exists in Poland and Hungary. In Poland, health care providers reported the vaccination status of individual age groups of children and adolescents once a year as of 31 December. Since 2009, information on vaccination has been available to any citizen who has an account in the E-Patient system operated by the Ministry of Health as part of their legal obligations.

In the period covered by audit, in Belarus, there was no centralised register of vaccinated persons in the audited period, automated information systems existed in individual health organisations that were used to count vaccinated people. It was possible to verify vaccination data at the territorial health authority of the place of residence, as well as to transfer information from the child's medical records for patients transferring to services at an adult clinic.

In Slovakia, every year as of 31 August, the Public Health Authority conducted an administrative control of compulsory vaccination, where, among other data, it summarized the level of vaccination. The creation of an online register of vaccinated persons is one of the tasks in progress of the National Plan for the Control of Infectious Diseases.

In planning, coordinating, and monitoring an immunisation programme, the status of the population's immunity to communicable diseases is ascertained (**immunological survey**). It has been carried out in various forms in all participating countries.

The timing and amount of research needed to assess the immunological effectiveness of vaccination in Belarus was determined by the Ministry of Health, depending on the epidemiological situation or the forecast of its development. The date has not been set by law. Efficacy is determined by a coefficient that considers data on the number of persons with post-vaccination antibody protection titres and in the unvaccinated (or placebo) group and the number of vaccinated and unvaccinated persons in the population. The last immunology study was conducted in 2019 against measles. Based on the results, vaccination of certain age groups of the population was subsequently conducted. Data on influenza incidence in 2018-2019 were also analysed, demonstrating a high level of immunisation efficacy.

In Poland, the assessment of the population's resistance status to infectious diseases was conducted annually by a specialised epidemiological surveillance unit, the National Institute of Health - National Research Institute. The assessment was based on a comparison of the vaccination status of persons vaccinated in the current year compared to the previous year.

In Slovakia, the immunological survey was performed on a representative sample of the population. The Public Health Authority was responsible for its implementation. On the basis of laboratory examination of blood samples, the sufficiency of antibody levels against the diseases under investigation was determined. In case of insufficient levels, changes in the vaccination calendar were implemented. The legislation does not specify the time intervals at which the immunological survey should be conducted. It has been conducted three times in the last 25 years - in 1997, 2002 and 2018. In view of the need to monitor the immune status of the population due to the spread of serious infectious diseases, the National Plan for Infectious Diseases foresees repeating the survey every five years in the future.

b. Refusal of the vaccination and solution of cases of the health damage after vaccination compensation - comparison

Despite states' efforts to intervene in favour of vaccination, there are groups of people who, for distinct reasons (other than health), refuse vaccination as a whole or just some types of vaccination. While in Slovakia, for example, during the period covered by audit, the rejection of the mumps, rubella and measles vaccine prevailed in the audited period, in Belarus rejection was not so clearly aimed at only one specific type of vaccine.

The countries participating in this audit had specific **legislative procedures** in place in the event of **refusal** of vaccination.

After an initial briefing by the general practitioner on the need for and reasons for vaccination, the persons concerned, or their legal representatives participated in further interviews. For example, in Belarus they attended immunology committee meetings, in Slovakia they were contacted by regional public health authorities.

If they continued to refuse vaccinations after the interview, in Poland and Slovakia they were fined. In Belarus, such persons are kept in the relevant register, but fines are not imposed on them.

The audit found that in Slovakia, regional public health authorities assessed cases on a case-by-case basis and did not impose fines in all cases of refusal. In Poland, it was found that primary care physicians did not report cases of avoiding vaccination and no recommendations were made by the staff of district sanitary and epidemiological stations despite frequent inspections of primary care facilities. NIK notes that the shortcomings will be remedied by the introduction of an electronic vaccination card, which is being developed as a functionality of the government's E-Patient system.

States have been looking into **the reasons for refusing** vaccinations, which are similar. In addition to cultural and religious reasons, people are afraid of the undesirable effects of vaccination and subsequent complications. They are concerned about the presence of toxic substances in vaccines and point to theories about possible link between vaccination and the emergence of various diseases. Antivaccination movements in individual countries, as well as groups promoting alternative medicine, have a major influence.

The current response to this situation in Poland is the project "Vaccination refusal as a challenge to national health policy, public confidence, public health, and family and social policies" of December 2020.

Belarus, Poland, and Slovakia dealt with the existence or absence of compensation schemes in the audit. None of these countries have specific schemes to compensate persons if their health is damaged because of vaccination. The Belarusian audit did not have data on possible claimants for compensation, and no funds were used for compensation. In Poland and Slovakia, such compensation could be recovered through civil court proceedings during the period under review. However, information on the resulting claims was not subsequently collected (e.g., in special registers, etc.). As an inspiration in this area, in July 2021 the Council of Ministers adopted draft Act on vaccination Compensation Fund.

c. National Statistics — achieving collective protection of the population

All participating countries recorded and evaluated data on population vaccination rates by disease in each year.

The following tables show the vaccination coverage in each country:

Table 1: Vaccination coverage in Belarus

Vaccine	Year				
	2015	2016	2017	2018	2019
Diphtheria, tetanus, whooping cough	99	98	97	97,1	97,7
Poliomyelitis	99	98	98	97,6	97,6
mumps, rubella, measles	99	98	97	98,3	98,2
Tuberculosis	97	98	98	98,3	97,3
Infectious hepatitis type B	99	96	98	98	97,2

Source: National Report

Table 2: Vaccination coverage in Hungary

Vaccine	Year				
	2015	2016	2017	2018	2019
Tuberculosis	99,9	99,8	99,8	99,8	99,8
Diphtheria, tetanus, whooping cough, haemophilic disease, polio (at month 2)	99,9	99,9	99,9	99,9	99,9
Pneumococcal invasive diseases (at month 2)	-	-	99,8	99,9	99,9
Diphtheria, tetanus, whooping cough, haemophilic diseases, polio (at month 3)	99,9	99,9	99,9	99,9	99,9
Diphtheria, tetanus, whooping cough, haemophilic disease, polio (at month 4)	99,9	99,9	99,9	99,9	99,9
Pneumococcal invasive diseases (at month 4)	-	-	99,7	99,8	99,8
Pneumococcal invasive diseases (at month 12)	-	-	99,6	99,9	99,8
Mumps, rubella, measles (at month 15)	99,9	99,8	99,9	99,9	99,9
Diphtheria, tetanus, whooping cough, haemophilic disease, polio (at 18 months)	99,3		99,7	99,6	99,6
Diphtheria, tetanus, whooping cough, polio (at year 6)	99,7	99,7	99,6	99,6	99,6
Mumps, rubella, measles (revaccination)	99,6	99,7	99,7	99,7	99,8
Diphtheria, tetanus, whooping cough (revaccination)	99,6	-	99,7	99,8	99,7
Hepatitis type B I.	99,6	99,7	99,7	99,8	99,8
Hepatitis type B II.	99,5	99,7	99,7	99,7	99,8

Source: National report and (2015, 2016 and 2017) publicly available information Ministry of HR

Table 3: Vaccination coverage in Poland

Vaccine	Year				
	2015	2016	2017	2018	2019
Diphtheria/tetanus	97,9	97,6	96,4	95,2	95,0
Whooping cough	97,8	97,6	96,4	95,2	94,9
Poliomyelitis	97,8	97,6	96,4	95,1	94,9
Pneumococcus	-	-	-	94,1	94,3
Mumps/rubella/measles	96,3	95,5	94,0	92,9	92,6
Haemophilic diseases	97,8	97,6	96,4	95,1	94,8
Hepatitis type B	99,2	98,8	98,4	97,8	97,5
Tuberculosis	99,4	99,2	98,9	98,4	97,5

Source: Polish Institute of Hygiene

Table 4: Vaccination coverage in Slovakia

Vaccine	Year				
	2015	2016	2017	2018	2019
Diphtheria, tetanus, whooping cough, infectious hepatitis type B, haemophilic diseases, polio	96,0	96,4	96,4	96,5	96,7
Pneumococcal invasive diseases	95,7	96,1	96,2	96,2	96,5
Measles, mumps, rubella	93,9	94,5	94,8	95,2	95,7

Source: National Report

For the combination of diseases contained in individual vaccines, the level of collective immunity has been set at 95% based on a WHO recommendation.

Based on the data given in the tables, it can be concluded that a sufficient level of collective immunity at national levels for individual diseases has been ensured during the period under review. An exception was the mumps/rubella/measles vaccination in Slovakia in 2015-2017, and Poland in 2017-2019, when the level of vaccination was below 95 % after the first year of vaccination. Poland did not achieve the necessary vaccination rate even for pneumococci, and in 2019 it was just below the level even for whooping cough, polio, and haemophilic diseases.

Given the current intensive population movement around the world, the introduction of infectious diseases into any country cannot be ruled out. It is therefore **essential to maintain the high vaccination** coverage of the paediatric population to date, to increase the vaccination coverage of adults and to pay particular attention to the vaccination of hard-to-reach population groups.

The prospect is **to extend the regular compulsory vaccination** of the paediatric population or selected groups of persons at elevated risk of infection against further infections, in line with WHO recommendations and in line with the vaccination in other EU Member States.

5. Efficiency of the measures to prevent a decrease in compulsory vaccination

a. Fulfilment of national and international obligations in the field of compulsory vaccination

The most important activity related to the promotion of immunisation of the population is the implementation of national immunisation programmes, the task of which is to eliminate the incidence of communicable diseases by consistently ensuring effective immunisation. This process involves numerous activities, the most important of which are vaccination, vaccination coverage monitoring, assessment of the immune status of the population, monitoring the incidence of diseases that can be prevented by vaccination, as well as monitoring of the circulation of causative agents in the population or in the external environment.

The implementation of national immunisation programmes was dealt with by all participating States. Many international activities have also been conducted to strengthen cooperation on vaccination, hesitancy in vaccination and refusal of vaccination. These programmes were run by various organisations (WHO, UNICEF, UN) as well as under the auspices of the EU.

During the audited period covered by audit, Belarus cooperated with the WHO based on the establishment of technical advisory cooperation. It also implemented a programme to achieve the indicator "Proportion of the target population covered by all vaccines included in their national program", which falls under the SDG - UN programme - SDGs.

Poland and Slovakia were involved in the implementation of WHO programmes - action plans for the elimination of measles and for the elimination of congenital rubella syndrome and rubella, Slovakia also took part in the implementation of the action plan to maintain poliomyelitis containment. In addition, Slovakia was involved in the EU's Joint Action on Vaccination project, which was tasked with strengthening EU cooperation in the field.

b. Measures in case of decreased vaccination, comparison and evaluation

As a result of rejection, the vaccination rate of the population decreases and thus collective protection against communicable diseases. This creates scope for the emergence of epidemics and the threat to the most vulnerable populations.

States are trying to reverse this trend, by educating on the importance of vaccination and constantly pointing out the benefits of vaccination, highlighting the possible consequences of unvaccinated children. The aim is to raise awareness among parents as well as of the younger generation, i.e. future parents (e.g. the project "Attitudes of future parents towards vaccination" implemented in Slovakia). There are high school sessions with students, as well as sessions with parents in maternity centres.

In Poland and Slovakia, the authorities responsible for vaccination (The Chief Sanitary Inspectorate in Poland and the Public Health Authority in Slovakia) participated in the support activities. They issued guidelines and recommendations, communicated through social media, prepared activities related to the European Immunisation Week initiative (Belarus is also part of it).

In Poland, an information campaign with the motto "Engraft in yourself the readiness to vaccinate" was launched in December 2017, followed a year later by a social campaign "Vaccinated and safe" (#zaszczepieniBezpieczni) to address doubts about vaccination in the face of conflicting views and false news. In March 2019, a competition for teachers was launched, where the task was to develop a lesson plan on infectious disease prevention.

Slovak hygienists have set up a web portal on vaccination, where parents can find expert information and opinions of experts. Under the Health Ministry, the organization "Healthy Regions" has been working, among other things, to increase participation in preventive check-ups and compulsory vaccination of marginalized Roma communities. Information related to the European Immunisation Week and immunisation was presented in Slovakia in regional media and in municipal radios, on websites, on info-panels located at the Public Health Authority of the Slovak Republic and regional public health authorities, in waiting rooms and in outpatient clinics of doctors, in the pre-school and school premises. Educational materials were also provided to field social workers who work with the Roma community on a daily basis.

All described activities are **unquestionable, meaningful, and** necessary. Despite the implementation of a number of support activities, their **sufficiency is questionable**. The Slovak audit pointed to the fact that there was no evaluation of which activities and how they were able to help in increasing the vaccination coverage of children and adults, or in the subsequent vaccination of unvaccinated children. It was not possible to assess whether the increase in vaccination coverage at that point was influenced by the activities of the immunisation programme or e.g. by the occurrence of an epidemic (e.g. in 2018-2019, when the events surrounding the measles epidemic in Slovakia helped to increase parental confidence in vaccination against them and subsequently increased interest in vaccination).

At the same time, at the end of this section, the Polish NIK noted that the activities conducted may be insufficient to prevent a further decline in the number of vaccinated due to the recent revival of anti-vaccination groups.

6. Availability of vaccines

a. Assurance of availability, monitoring and control

During the period covered by audit, access to compulsory vaccination vaccines was free of charge in all countries concerned during the audited period.

The method of obtaining vaccines in the audited states was twofold. **Centralised** in Belarus, Hungary and Poland, **decentralised** in Slovakia (since 2005).

In the centralised system, vaccines were procured by the State through a designated authority through public procurement. In the decentralised system, vaccines were categorised in the same way as other medicines and were available from pharmacies, which ordered them based on orders from vaccinating doctors.

In Belarus and Poland, the Ministry of Health was responsible for procuring vaccines, in Hungary the national Chief Medical Officer (until 30 September 2018, the Ministry of Human Resources).

The strength of a centralised system is the systematic planning of consumption. The production and technological cycle of vaccines differs from that of conventional medicines, with production planning required in some cases up to 1.5 years in advance. Therefore, predictability of consumption is important, i.e. determining the expected annual volume of vaccines needed to vaccinate a selected population group.

In Belarus, planning was carried out for the following year through the Ministry of Health, together with the regional executive committees and the Minsk City Executive Committee. In public procurement, account was taken of the availability of immunological drugs, which could be assessed based on the weekly balances of the Republican Center for Hygiene, Epidemiology and Public Health. The plan was also based on a population register, which was updated twice a year for children under the age of eighteen.

During the period under review, Hungary has been planning the necessary number of vaccines through the National Public Health Centre (until 30 September 2018 through the organisational units of the Ministry of Human Resources). They also prepared procurement plans for each year.

In Poland, the demand for vaccines was initially addressed by the district and regional state sanitary inspectors, on this basis the Chief Sanitary Inspector submitted a request to the Minister of Health 6 months in advance (in June of the year preceding the year of the requested purchases) considering the need for vaccines. The projected changes in the epidemiological situation in Poland and the world were also considered in determining demand. The request also took into account the need to maintain vaccine reserves for at least three months of vaccination in order to mitigate potential supply shortfalls (e.g. due to the cancellation of tenders, withdrawal of a particular batch of vaccines, delayed delivery of vaccines, etc.).

The Slovak decentralised system did not address planning. The acquisition of vaccines was not subject to public procurement, thus the whole process avoided any possible comment procedures from vaccine import bidders. On the other hand, there were repeated local and national vaccine shortages, which disrupted the smooth running of compulsory vaccination and obstructed compliance with the deadlines set by the vaccination calendar.

In the process of planning, but also of realization of vaccination, it **is important to have information on currently available vaccines**. States have dealt with this issue in diverse ways.

On the 15th day of the month following the reporting quarter, RUE Belpharmacia (responsible for the purchase of immunobiological drugs in Belarus) submitted information to the Ministry of Health on the balances of drugs purchased from the Republic's budget (about half of all vaccines purchased). The monitoring of the availability of the balances of these immunobiological drugs was carried out by the vaccinating health care organisations, which entered the data into an automated information system to support public procurement procedures.

The management of vaccine stocks in Hungary was conducted through the subsystem of vaccination logistics and vaccines of the National Social Information System.

In Poland, a procedure for real-time monitoring of vaccine availability was in place during the period under review. Stocks were monitored through an electronic vaccine distribution surveillance system. The system is able to identify risks related to the continuity of vaccination, detect faulty batches of vaccines and flexible distribution of vaccines across the country based on demand.

In Slovakia, due to the existing system of vaccine procurement, it was not possible to ascertain the availability of vaccines in real time. Only information on imports, interruptions, or cancellations of supply of human medicines was available. The issue was dealt with by the State Institute for Drug Control, on whose website this information was available. Once the notification obligation of the holders of the authorisations for the distribution of medicines (and therefore vaccines) had been fulfilled, it was not possible to sanction the shortfalls.

b. Vaccine delivery and storage control

The delivery and subsequent handling of vaccines has been dealt with procedurally in the participating countries.

In Belarus, a programme of information and analytical system "Provision of medicines" was used during the controlled period, from which information on the supply of any medicine purchased from the national budget could be obtained. Compliance with the cold chain, as well as overall control of vaccination, was carried out by chief state sanitary doctors of the regions and the city of Minsk. Storage was provided by regional organizations of the Belpharmacia system.

The national Chief Medical Officer was responsible for handling vaccines and following the cold chain in Hungary.

Purchased vaccines in Poland were transported and stored in accordance with the cold chain requirements and under the conditions defined by pharmaceutical law. The transport was coordinated by the Chief Sanitary Inspectorate, the vaccines were distributed to the warehouses of regional sanitary and epidemiological stations across the country, then transported to district stations, which handed over vaccines to healthcare providers carrying out the compulsory vaccinations.

As part of the annual evaluation of administrative control of vaccination, the Public Health Authority of the Slovak Republic provides data on cold chain control collected from paediatric districts. It checked the availability of suitable refrigerators intended solely for the storage of vaccines, a record of the temperature in the refrigerator, the continuity of its control, compliance with the cold chain (transport of vaccines from the pharmacy to the paediatric outpatient clinic).

7. Conclusion

Professional cooperation is always a possibility of development and new impulses. Despite the demanding situation during which this audit was carried out, the agreed content was fulfilled, and all the topics consulted were covered. International comparison has made it possible to obtain examples of best practice and to be inspired to reassess national systems and procedures. The audit also highlighted possible new topics that will need to be addressed in the future.

Annex 1: List of abbreviations

Abbreviation	Full text
Belarus	Republic of Belarus
EU	European Union
NIK	Supreme Audit Office of Poland (Najwyższa Izba Kontroli)
UN	United Nations
Poland	Republic of Poland
SR, Slovakia	Slovak Republic
UNICEF	UN Children's Fund for Emergency Aid
WHO	World Health Organisation

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