

To:

**The Minister of Health**

**The Chief State Health Inspector**

**The Director of the National Health Insurance Fund (NHIF)**

**The Chair of the National Assembly Healthcare Committee**

**The Chair of the National Council on Prices and Reimbursement of Medicinal Products (NCPRMP)**

**The Chair of the State Agency for Child Protection (SACP)**

**The National Ombudsman**

**The Association of the Research-based Pharmaceutical Manufacturers in Bulgaria (ARPharM)**



# DECLARATION ON THE IMPROVEMENT OF VACCINE PROPHYLAXIS IN BULGARIA

**First National Conference on Vaccine-Preventable Diseases  
11–13 November 2022**

As one of its greatest achievements during the last one hundred years, medicine has established lasting control over numerous infectious diseases that had previously brought death and suffering to millions of people. The enormous efforts made to develop safe and effective vaccines target the protection of both the individual and society as a whole.

Vaccination is one of the most powerful and cost-effective measures in the sphere of public health that were developed in the 20<sup>th</sup> century and remains an essential tool for the primary prevention of communicable diseases. At present, vaccination can prevent 28 of the most dangerous communicable diseases known to mankind. Unfortunately, in 2020 the World Health Organization (WHO) reported a significant decline in vaccination coverage worldwide. According to official statistics:

- The global coverage of immunizations against diphtheria, tetanus and pertussis (DTP3) fell from 86% in 2019 to 83% in 2020;
- 23 million children (3.7 million more than in 2019) missed out on basic immunizations during their first year of life (for the first time since 2009);



- The number of children with incomplete immunizations increased to 3.4 million;
- As few as 19 vaccine novelties were reported, which was half of the annual new arrivals over the last 20 years;
- 1.6 million girls did not receive a complete HPV vaccine course in comparison to the previous year.

WHO regards an increase of the vaccine coverage as a key priority in preventing epidemic outbreaks of vaccine-preventable diseases in children in 2023.

Within the framework of the First National Conference on Vaccine-Preventable Diseases (11–13 November 2022), a number of issues were outlined and recommendations were formulated for an improvement of vaccine prophylaxis in Bulgaria. More than 50 research papers were reported and presentations were made, and numerous discussions were held, involving a large number of professionals:

- 200 in-person delegates
- 100 online delegates

The high level of the forum and the broad range of professionals who took part in it provide grounds to sum up the challenges identified and the proposals put forward for an improvement of vaccine prophylaxis in Bulgaria.

## **Challenges**

### **1. Organizational problems**

1.1. Insufficiently effective electronic system accounting for medical activities, including the administration of immunizations.

1.2. Lack of a standardized immunization refusal form to be signed by persons who refuse to be vaccinated and revaccinated without medical reasons, which clearly states the potential risks and restrictions that may ensue for the patient/parent.

1.3. Insufficient control upon enrolment in a cr che, kindergarten or school. Many private kindergartens ignore the health requirements for children.

### **2. National Immunization Calendar**

2.1. Limited number of manufacturers entering bidding procedures for supply (one or, at most, two per lot).

2.2. Doubly restrictive policy towards vaccine prices: first, lowest price under the Positive Drug List (international referencing) and, second, lowest price (the only award criterion in an open procedure under the Public Procurement Act).

### **3. National immunization programmes under Article 82(2) of the Health Act**

3.1. Slow feedback from the NHIF about the vaccines that have been administered and accounted for.

3.2. Small number of provider types.

3.3. Unclear role of the national programmes' Coordination Councils with regard to control over the implementation of the national immunization programmes.

3.4. Short period for the implementation of the Influenza Programme (1 October–31 December).

3.5. Too narrow target age groups under the national programmes.

### **4. Vaccines freely available for sale**

4.1. Small number of vaccine manufacturers with a limited number of products.

4.2. Complicated process of registering and referencing vaccine prices, which



makes vaccine manufacturers largely lose interest in the Bulgarian market.

4.3. Sales on the pharmacy free market restricted to 4 out of a total of 13 recommended immunizations.

4.4. Risk of an epidemic outbreak (hepatitis A) and public pressure (yellow fever, meningococcal infection) when key products are unavailable.

#### **5. Low level of public awareness**

5.1. Lack of a targeted State policy and media-backed initiatives to clarify and educate the public about the gravity of vaccine-preventable diseases and the benefits of vaccination.

5.2. Upsurge of anti-vaccine movements and moods in society.

5.3. Citizens' mistrust of doctors and other medical specialists engaged in vaccine prophylaxis. Existence of unfounded fears and heightened anxiety in the public regarding vaccines.

#### **We propose the following solutions:**

##### **SOLUTIONS FOR IMPROVEMENT OF VACCINE PROPHYLAXIS**

1. Maximize the capabilities of the National Health Information System and synchronize it with the NHIF in order to avoid the double accounting for administered vaccines. All vaccines administered to all citizens must be reported in a single system with different levels of access.

2. Introduce clear criteria and sanctions in the legislation of the Republic of Bulgaria for persons (including parents) who have not received immunization or have not had their children immunized with vaccines of the mandatory immunization calendar. The incentives must be clear, and the sanctions must be soft, targeted at every citizen.

3. We support the robust control by the Regional Health Inspectorates over all children's and educational establishments so as to oversee the health requirements in the educational system, especially the requirements for administered immunizations. Those requirements guarantee the life and good health of every child.

4. We encourage stronger vaccines promotion according to the national mandatory immunization calendar among parents of children in vulnerable communities, in order to decrease the school drop-out rates of those children.

5. Offer incentives to the National Immunization Programme providers for an increased level of coverage. Include the criteria in the National Framework Agreement. Subsequently transpose the incentives, as set in the National Framework Agreement, also into the individual contracts for primary non-hospital medical care concluded between the NHIF and the medical-treatment facilities for primary non-hospital medical care.

6. Deliver in due time the requisite quantities of vaccines to general practitioners. Implement more effectively the annual/biennial plans for the requisite quantities of vaccines. Ensure the overall strategic supply. If necessary, enlist the pharmaceutical industry and medicines' distributors in the effort.

7. Arrange receipt of the vaccines as ordered according to general practitioners' needs. Organize delivery of the vaccines as ordered at the address of their practice, saving general practitioners precious time that they could otherwise spend attending to their patients. Pre-plan the quantities on the basis of the Population National Database of the Civil Registration and Administrative Services Directorate General and current confirmation of the quantities concerned on the part of general practitioners.



8. Enforce responsibility with regard to vaccine prophylaxis: Medical specialists may not refuse to administer vaccines and must actively persuade their patients to receive immunization. A physician who refuses to administer vaccines and/or who dissuades patients must be sanctioned, including by withdrawal of the licence to practise medicine.

9. Improve logistics: Build up the stocks of vaccines covered by the mandatory immunization calendar. Provide timely information on the replacement or introduction of a new vaccine. The Ministry of Health must deliver training on handling the programme.

10. Update, from time to time, Ordinance No. 15 on Immunizations and the eligibility criteria for entry into bidding procedures, taking into account the current serotypes for Bulgaria on the basis of local epidemiological data.

11. Increase the budget of the national programme for influenza vaccines (2023–2027). The demand for influenza vaccines in the autumn of 2022 was for quantities double those set in the national programme and imported.

12. Introduce pneumococcal vaccines for adults aged over 65.

13. Broaden the cohorts consisting of girls and boys aged between 9 and 18 with HPV vaccines provided under the national programme, and make the vaccine available for sale on the free market to the rest of the age groups.

14. Include chickenpox, rotavirus and HPV vaccines for both sexes of the 9–18 age group in the mandatory immunization calendar.

15. Add COVID-19 vaccines to the list of vaccines recommended for all patients with underlying chronic respiratory, cardiovascular, endocrine, rheumatic and haematological diseases, as well as for overweight patients.

16. Set up mechanisms to increase the coverage of national programmes by offering results-based incentives to primary non-hospital medical care providers.

17. The health authorities must develop a (communication) strategy with the support of narrow specialists and organizations in order to build public confidence in vaccines and increase the vaccination coverage.

18. Improve doctors' effective interpersonal communication skills in order to induce a social and behavioural change in citizens/patients by means of targeted specialized training events for medical specialists.

Decision-making in public health policies should be guided by the inexhaustible expert resources of the people working in the Bulgarian healthcare system. The National Conference on Vaccine-Preventable Diseases seeks to pool these resources and provide a platform for addressing the challenges but also for arriving at solutions and recommendations.

We appeal to you: take into consideration the tenets formulated above, and let us work together for an improvement of vaccine prophylaxis in Bulgarian for the sake of sustainable public health.

