

## **TASKS AND WORKING METHODS OF THE IMMUNIZATION ADVISORY GROUP**

### **1. The objective and function of the Immunization Advisory Group**

The Immunization Advisory Group (IAG) acts as an advisory body of the National Institute for Public Health (NIJZ) in various professional capacities and for strategic decisions in the field of vaccine preventable diseases and in the design of vaccination programmes. The IAG members are appointed by the resolution by the Director of the NIJZ.

### **2. NIJZ assignments in the field of vaccination**

The function and assignments of the NIJZ in the field of vaccination are defined in the Articles 5, 11 and 25 of the Infectious Diseases Act (ZNB, Ur. L., No. 33/2006-UPB1) and include:

- collection of data on vaccine preventable diseases and data on population immunization,
- epidemiological monitoring of disease patterns and their causes in the country and internationally,
- the implementation of studies on population immunity and/or susceptibility to vaccine preventable diseases,
- constant monitoring of new developments in the field of vaccination (in particular the development and availability of emerging information on vaccines, which are already in use and of new vaccines). Based on estimates of disease risk, spread, and the disease burden, the Center for Infectious Diseases (CNB) of the NIJZ assesses the possibility of changes or additions to the Programme of immunoprophylaxis and chemoprophylaxis or the introduction of new vaccines;
- monitoring side effects following vaccination,
- proposing the annual programme of vaccination and protection using medicinal products,
- provision of vaccines (acquisition and distribution of vaccines and specific immunoglobulins)

NIJZ in the field of vaccination pursues the following objectives:

- provide a professional basis for a safe vaccination system,
- provide information to the general public,
- provide professional input for policymaking in the field of public health,
- provide independent expert opinions.

### **3. IAGs work**

The function IAC members is to consult on priority assignments for the coordination of vaccination, and to formulate opinions on highly specialized topics, which include Pediatrics, Infectology, Immunology, Epidemiology, Allergology, Neurology, Neonatology, Ethics, Pharmacovigilance, Pharmacoeconomics. This will inform the preparation of national recommendations, instructions, answers, and advice in a relation to specific questions and issues to act as starting points for the selection of vaccines and the successful introduction of new vaccinations.

IAG advises the NIJZ on the following assignments or topics:

- short-term and long-term assignments in the vaccination programme - setting priorities;

- national professional guidance in the field of vaccination - especially for specific conditions and target groups;
- reinforced epidemiological monitoring of vaccine preventable diseases;
- side effects of vaccination;
- setting priorities for research and development;
- selection of vaccines;
- materials with information about vaccination for the general public.

#### **4. IAGs structure**

The Group is composed of members who are appointed into the group by the Director of NIJZ from the experts with experience in the field of vaccination and vaccines. The Group is composed of members, experts with experience in the field of vaccination and vaccines, who are appointed into the group by the Director of NIJZ. The members are appointed according to professional references and not as representatives of sectors or institutions.

The President is elected among the members who simultaneously vote his deputy.

Membership is unlimited and can be terminated at any time without giving reasons.

#### **5. Working methods of the IAG**

The IAG meetings are convened by the President of the IAG, and in his absence, his deputy, at the initiative of the NIJZ or at its discretion. To the meetings of the IAG, apart from the members, the following people are continuously invited: the Director of NIJZ, Head of the Centre for Infectious Diseases of the NIJZ, vaccination coordinators and other experts in the field of vaccination and vaccines of the NIJZ.

Depending on the topic, the IAG may invite other experts to the meetings (employees of NIJZ or other institutions).

IAG meetings are held at least four times a year, more only if necessary. Beside of the IAG meetings, the work of the IAG can also be proceeded via telephone/video conference or by correspondence (via e-mail, etc.). To pay the expenses of members associated with their participation in the meetings of the VAG will be liable NIJZ according to regulations.

At the meetings of the IAG, meeting minutes are written and all members of the VAG and the participants of the meeting will receive them. All meeting minutes of the VAG are archived by the CNB of the NIJZ. The conclusions of the meetings are posted on the NIJZ website.

The materials, opinions, and other IAG products will be approved by the coordination meeting or via telephone/video conference or by correspondence (via e-mails, etc.) before the distribution. Decisions of the VAG are normally taken by consensus. If no consensus is reached, the dissenting opinions are recorded in the meeting minutes.

The IAG offers support to the CNB of the NIJZ, which provides professional and technical support and ensures that it takes into account the requirements for excellence, independence, and transparency of the work. The CNB of the NIJZ also provides materials and meeting minutes.

Members of the IAG and other invited experts who will participate in meetings or the IAGs work, will submit a written statement regarding compliance with the confidentiality and security of personal data and the declaration of conflict of interest. Any member or other participant will be required to attend the meetings depending on the topic and will announce any interest that could present a real, potential or virtual dependency or bias. In a case that it is proven that a member or a participant in relation to the subject matter cannot work independently, it will not be involved in decision-making process.

The IAG may take the initiative to the NIJZ to organize consultations, and if necessary, to supplement an expert opinion.

When meetings with manufacturers of vaccines will be required, the NIJZ will provide an opinion to the Public Agency for Medicinal Products and Medical Devices. At such meetings the IAG will not accept any decision or notions.

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