

THE ESTABLISHMENT OF THE NATIONAL ANTIBIOTIC PROGRAMME

The Ministry of Health, based on Resolution of the Government of the Czech Republic No. 595 of May 4, 2009 on the establishment of the National Antibiotic Programme¹ and in accordance with the contents and targets of the Council Recommendation of 15 November 2001 on the prudent use of antimicrobial agents in human medicine (2002/77/EC)² and Council Recommendation of 9 June 2009 on patient safety, including the prevention and control of healthcare associated infections (2009/C 151/01)³,

establishes the National Antibiotic Programme (hereafter referred to as NAP) and specifies its scope, objectives, activities, functions and organizational structure.

Article I

Points of departure, Background

1. Ever increasing and rapidly spreading resistance of microbial agents poses a high risk to the efficacy of antimicrobials. **Within the short period since 2000, antimicrobial resistance of some important infectious agents has risen even by tens of percent.** The dangerous trend is observed in most European countries including the Czech Republic where the situation with reference to some pathogens is one of the worst in Europe. Antibiotic resistance is demonstrably associated with increased mortality, morbidity, and healthcare costs and therefore is a risk to patient safety and to the financial sustainability of the healthcare system.
2. **The cause** of the increased antibiotic resistance is **overuse and misuse of antimicrobials** in both human and veterinary medicine as well as failures in the prevention and control of infections facilitating the spread of resistant microorganisms in healthcare settings and among the general population.
3. **Studies on antibiotic prescription quality assessment** conducted in the Czech Republic over the past decade have shown a high frequency of inadequate use of antimicrobials in primary, inpatient, and outpatient care. This fact is an important threat to the maintenance of the efficacy of antimicrobials in the Czech Republic. Extra costs incurred in this regard by the public health insurance system are estimated to be at least CZK 1 milliard per year.
4. This situation requires **prompt implementation of systemic, evidence-based and cost-effective measures** at the national, regional and local levels. In line with the principles laid down by the above-mentioned EU Council recommendations, it is necessary to establish a complex, intersectoral and interdisciplinary programme covering both human and veterinary medicine – the National Antibiotic Programme.

¹

[http://kormoran.vlada.cz/usneseni/usneseni_webtest.nsf/0/6DFE372AE0102BC7C12575A8004335A7/\\$FILE/595%20uv090504.0595.pdf](http://kormoran.vlada.cz/usneseni/usneseni_webtest.nsf/0/6DFE372AE0102BC7C12575A8004335A7/$FILE/595%20uv090504.0595.pdf)

² <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:034:0013:0016:EN:PDF>

³ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2009:151:0001:0006:EN:PDF>

5. **Antibiotic resistance prevention and control are cost effective.** Reasonable use of antimicrobials and effective infection control result in improved health care quality and higher patient safety and at the same time in cost savings. The establishment of the NAP is therefore in line with the effort to find savings within the public health system, especially in the face of the limited public health insurance sources that are available.

Article II

NAP objectives and principles

1. **The objective** of the NAP is to ensure a long-term available, effective, safe and cost-effective antibiotic treatment for patients with infectious diseases. It can be achieved primarily by promoting good practice in the use of antimicrobials to prevent overuse, by effective infection prevention and control to prevent the spread of resistant pathogens in health care settings and among the general population, and by providing education to and raising awareness of both the professional and general public in this issue.
2. **The basic NAP principle** is the so-called intersectoral coordination mechanism whose purpose is particularly to ensure effective coordination of activities between human and veterinary medicine and all stakeholders who may play a role in prioritizing targets and achieving NAP objectives. The stakeholders can play different roles (governing, coordination and executive, consulting or advisory, media-related, etc.).

The stakeholders are namely:

- a) **State administration:** Ministry of Health; Ministry of Agriculture; regional state administration authorities and their representatives (heads of public health departments); Ministry of Education Youth and Sports; and Ministry of the Environment.
- b) **National public health institutions:** National Institute of Public Health; State Institute for Drug Control; regional health protection and promotion authorities; and interested reference laboratories.
- c) **National veterinary institutions:** Institute for State Control of Veterinary Biologicals and Medicines; State Veterinary Administration and its regional offices; and interested reference laboratories.
- d) **Professional organizations:** J.E. Purkyně Czech Medical Association (hereafter referred to as JEP CMA) and its Antibiotic Policy Subcommittee (hereafter referred to as APSC), professional societies, professional working groups, professional associations; Czech Medical Chamber; Czech Pharmaceutical Chamber; Czech Dental Chamber; Czech Nurse Association; Veterinary Doctors Chamber; etc..
- e) **Health care payers:** Health insurance companies and their common bodies (e.g. Union of Health Insurance Companies of the Czech Republic, Drug Committee of Health Insurance Companies, National Reference Centre, etc.) and possibly other stakeholders involved in health care funding.
- f) **Health care settings:** inpatient care settings including long-term care settings, outpatient care settings and primary care settings; Association of Hospitals, etc.

- g) **Academic institutions:** faculties of medicine and interested universities; Veterinary and Pharmaceutical University Brno; Institute for Postgraduate Medical Education; National Centre of Nursing and Non-Medical Health Professions, etc.
 - h) **Scientific institutions: Academy of Sciences of the Czech Republic** and its selected centres; grant agencies; and interested academic centres.
 - i) **Other stakeholders:** patient organizations; mass media; media agencies; interested non-profit organizations, etc.
3. Any **NAP activities shall be carried out independently of the pharmaceutical industry**, shall comply with the ethical principles and there can be no conflict of interest.

Article III NAP activities and functions

1. NAP principles and priorities are defined in the **long-term strategy** formulated by the NAP Central Coordination Group (see Article IV, paragraph 2) and approved by the Ministry of Health (hereafter referred to as MoH) in cooperation with the Ministry of Agriculture (hereafter referred to as MoA).
2. NAP activities are conducted at all levels in accordance with the **Action Plans** where the priorities for a 2-4-year period are defined, including the legislative, financial, personnel, and technical framework to be met for their completion. These Action Plans are formulated by the NAP Central Coordination Group (hereafter referred to as NAP CCG) that proposes the resources and terms and conditions needed for their completion. Based on a NAP CCG proposal, the Action Plan is approved by the MoH in cooperation with the MoA.
3. The Action Plan is implemented by the NAP CCG in cooperation with regional coordination groups and antibiotic centres (see below).

The NAP major activities and functions are as follows:

- a) **To formulate** and regularly update **the principles of the national antibiotic policy** in order to: (i) ensure adherence to good practice in therapeutic and prophylactic use of antimicrobials, (ii) work out and update a binding list of essential antimicrobials (for the MoH) and (iii) prepare background information for drug prescription restriction within the categorization of antimicrobials.
- b) **To monitor and analyze antibiotic resistance** at the local, regional and national levels with the aim of obtaining systematic data needed for effective antibiotic resistance prevention and control, including the assessment of the effect of the measures taken (the methods for antibiotic resistance surveillance are defined in the respective methodical guidelines „Surveillance of bacterial resistance to antimicrobials“ created in cooperation of the National Reference Laboratory for Antibiotics, hereafter referred to as NRL for Antibiotics, with APSC).
- c) **To monitor and analyze structured antibiotic consumption and use** at the local, regional and national levels with the aim of obtaining systematic data to eliminate antibiotic overuse and misuse and to assess the effect of the measures adopted (the methods for antibiotic consumption surveillance are defined in the respective methodical

guidelines „Antibiotic consumption surveillance“ created in cooperation of the Coordination Centre for European Surveillance of Antibiotic Consumption, hereafter referred to as CC ESAC, with APSC).

- d) **To implement** effective systemic **measures aimed at ever improving the quality of antibiotic use** in both human and veterinary medicine.
- e) **To implement** effective systemic **measures aimed at infection prevention and control** in the general population and hospitals with an emphasis on the prevention of transmission and spread of multidrug resistant pathogens.
- f) **To educate the general public and to raise their awareness** in an effort to increase their co-responsibility for an adequate use of antibiotics and the prevention of antibiotic resistance.
- g) **To educate the professional public** in prudent use of antibiotics and principles of antibiotic resistance prevention and control, with the relevant leading experts independent of the industry being the guarantors.
- h) **To promote science and research** in the area of antibiotic resistance, i.e. fundamental and applied research and projects focused on public health protection and health care quality.
- i) **To coordinate the international cooperation of the Czech Republic** in the areas of prudent use of antibiotics and antibiotic resistance prevention and control. The Czech Republic cooperates in particular with the European Centre for Disease Prevention and Control (hereafter referred to as ECDC) and World Health Organization (hereafter referred to as WHO) and participates in the relevant international projects such as the European Antibiotic Resistance Surveillance System (hereafter referred to as EARSS) and European Surveillance of Antibiotic Consumption (hereafter referred to as ESAC). The organization of the international Antibiotic Awareness Day (hereafter referred to as EAAD) is also part of the international cooperation agenda.

Article IV

NAP organizational structure

1. The NAP structure includes **units with the governing, coordination and executive functions at the national, regional and local levels.**

The main NAP organizational units are as follows:

2. **NAP Central Coordination Group (NAP CCG)**

To govern the NAP, an interdisciplinary and intersectoral central coordination group that is an advisory body of the Minister of Health was established according to provisions of Article 17 of the MoH Organization Rules.

- a) NAP CCG members:
 - 1 representative of the MoH section of public health protection and promotion
 - 1 representative of the MoH health care section
 - 1 representative of the MoH health insurance section

- 1 representative of the State Institute for Drug Control
- 4 representatives of the National Institute of Public Health (hereafter referred to as NIPH), 2 of these representatives from NRL for Antibiotics, 1 from the NIPH board of directors and 1 head of the NAP Secretariat
- 5 APSC representatives (from the areas of medical microbiology, clinical pharmacology or clinical pharmaceuticals, clinical disciplines, primary health care, and infection prevention and control)
- 2 MoA representatives (1 for the Institute for State Control of Veterinary Biologicals and Medicines and 1 for the State Veterinary Administration of the Czech Republic)
- 1 representative of the Association of Health Insurance Companies of the Czech Republic.

The NAP CCG members are appointed and removed by the Minister of Health based on a written proposal submitted by the unit whose representative the member is.

The NAP CCG activities are governed by the rules of procedure.

The NAP CCG activities are funded from the NIPH budget and the regular monthly meetings of the NAP CCG take place at the NIPH. The NAP CCG members are not entitled to financial remuneration for their activities as such.

b) The NAP CCG functions are as follows:

- **To formulate long-term strategy** of the NAP and its **Action Plans**, to propose necessary resources and terms and conditions for their completion, to supervise their completion including the projects carried out within particular points of the Action Plan, and to assess the results.
- To participate in the **preparation of the legislative and methodical background** for NAP activities.
- **To formulate the principles of the national antibiotic policy** in cooperation with the APSC, including the recommended procedures, and to support their implementation. To coordinate the cooperation between institutions, organizations and other stakeholders involved in the areas of antibiotic use and antibiotic resistance prevention and control.
- **To coordinate the education and awareness raising for the professional and general public** in prudent use of antibiotics and antibiotic resistance prevention independently of the pharmaceutical industry. To ensure the distribution of information on NAP activities and priorities.
- **To issue annual reports on NAP activities** to be submitted to the Minister of Health and Minister of Agriculture and to be published on the NAP web site. The annual report provides detailed information on meeting the action plan points and presents outputs of antibiotic resistance surveillance and antibiotic consumption surveillance in human and veterinary medicine.

3. National Antibiotic Programme Secretariat (NAPS)

- a) **The National Antibiotic Programme Secretariat** that falls directly within the competence of the NIPH board of directors has been established at the NIPH for administrative and organizational support of NAP activities in accordance with Resolution No. 595 of the Government of the Czech Republic.
- b) The NAPS **supports** primarily administrative, coordination and organizational activities of NAP CCG, completion of NAP Action Plans, and projects the guarantor of which is the NAP, including awareness-raising and education campaigns.
- c) The NAPS **mediates** the communication between NAP organizational units.
- d) The NAPS **keeps** the overview of antibiotic centres.
- e) The NAPS **ensures** administrative support of surveillance programmes the guarantor of which is NAP.
- f) The NAPS **works out** annual NAP reports and edits the NAP website.
- g) The NAPS **has been involved** in international cooperation within the scope of NAP activities.
- h) To meet the needs of the current Action Plan, the NIPH is responsible for an adequate personnel, financial and technical support to NAPS activities.

4. **NAP regional coordination groups (NAP RCGs)**

- a) The NAP concept requires the creation of the NAP regional coordination groups (NAP RCGs) whose task is **to coordinate NAP activities at the regional level** in cooperation with the NAP CCG and antibiotic centres.
- b) The NAP RCGs are involved in analogous activities and functions at the regional level to those of NAP CCG. They consist mainly of the representatives of the regional antibiotic centres located in the respective region, representatives of the regional health care authorities, regional representatives of the State Veterinary Administration, representatives of public health settings, representatives of the regional subsidiaries of the health insurance companies, and representatives of the regional public health protection and promotion authorities.

5. **Antibiotic centres (ACs)**

- a) **The NAP executive structures at the local level** are the antibiotic centres engaging in individual programmes in the field medical practice.
- b) **The ACs actively promote and control the adherence to the principles of good antibiotic practice** for the sake of prudent use of antibiotics in inpatient, outpatient and primary health care.
- c) **The ACs ensure the collection and analysis of data** on local and regional epidemiology of antibiotic resistance and indicators of antibiotic consumption and use.
- d) **The ACs provide background information relevant to antibiotic resistance surveillance** at the national and international levels.
- e) **The ACs coordinate the creation and updates of local strategies for antibiotic use** based on the national recommendations the guarantor of which is APSC.

- f) **The ACs** engage in the **education and awareness raising of both the professional and general public** and prevention and control of the spread of multidrug resistant pathogens and infections associated with in-hospital care.
- g) To execute the above-mentioned functions, **the ACs shall have a direct access to the services of a medical microbiology laboratory** which provides clinically relevant data for targeted antibiotic therapy and antibiotic resistance surveillance.
- h) **The ACs activities are regulated by special guidelines** (Guidelines for the activities of antibiotic centres in the Czech Republic). The overview of the ACs is kept by the NAPS.
- i) In the **veterinary area, certified AC veterinary laboratories** have been established with the purpose to diagnose causative agents of infectious diseases in animals and to monitor their resistance status. The ACs activities are governed by the State Veterinary Administration and National Reference Laboratory for Antibiotics.

6. **National Reference Laboratory for Antibiotics** (NRL for Antibiotics)

- a) **The NRL for Antibiotics provides reference services and guidance** in laboratory methods and antibiotic resistance surveillance.
- b) In cooperation with the network of local microbiology laboratories integrated in the Working Group for Antibiotic Resistance Surveillance, the **NRL for Antibiotics organizes national antibiotic resistance surveillance**, including typing of strains by molecular epidemiology methods.
- c) **The NRL for Antibiotics provides epidemiological data for formulating the principles of the National Antibiotic Policy** and in cooperation with the ECDC, ensures the participation of the Czech Republic in the EARSS and other related projects.
- d) **In the veterinary area**, analogous activities are conducted by the **NRL for Antimicrobial Resistance** that cooperates with the NRL for Salmonella (State Veterinary Institute in Prague) and NRL for Campylobacters (State Veterinary Institute in Olomouc). The system of veterinary NRLs is connected to the central Community Reference Laboratory for Antimicrobial Resistance in Copenhagen.

7. **Antibiotic Policy Subcommittee** (APSC) of the **J.E. Purkyně Czech Medical Association**

- a) **The APSC** is part of the organizational structure of the J.E. Purkyně Czech Medical Association. It provides **the expert background** for the NAP activities in antimicrobials and antibiotic resistance, especially in the issues of recommended procedures independent of the pharmaceutical industry (consensus on antibiotic use, treatment and prophylaxis of selected groups of infections, and antibiotic resistance prevention and control) as well as in the categorization of antimicrobials (unrestricted and restricted antibiotics).
- b) **The APSC formulates the national antibiotic policy principles**, with the professional associations acting as opponents and the J.E. Purkyně Czech Medical Association as the guarantor of consensus. The APSC groups the experts delegated by the professional associations in the areas of medical microbiology, public health and epidemiology, clinical pharmacology, clinical pharmaceuticals, infectious disease medicine, pediatric medicine, general medicine for children and adolescents, and general medicine. The APSC members are the coordinators of the European projects organized by the ECDC and DG SANCO (EARSS, ESAC, IPSE, and ABS International), veterinary medicine

representatives and the national representative for the area of antibiotic resistance at the ECDC.