

COMPENDIUM OF NATIONAL ACTIVITIES

BULGARIA

Measures to Improve Biosafety and Biosecurity

- With a Decision of the Council of Ministers from 2006 *only the Director of the National Center of Infectious and Parasitic Diseases / NCIPD / is allowed to give a permission/certificate for import and export of bacterial, viral and parasitic strains* for experimental, clinical and educational needs.

- On the base of a *very successful realization of twining projects with Netherlands and Italy / Phare projects 2006-2008 /* for strengthening the combat against infectious diseases the *National Center of Infectious and Parasitic Diseases / NCIPD /and the 28 Regional Inspectorates for Prevention and Control of Public Health/ RIPCPH / received a needed equipment for contemporary identification of highly pathogenic bacterial and viral agents* with potential to be used as biological weapons.

- As a part of the above mentioned twining projects *very intensive post graduated educational program was starting 2006-2008 for the epidemiologists, microbiologists and virologists working in the field of the surveillance of infectious diseases* in the country focused on the early warning system and the build up of the national computerized network for this purpose able to be linked with the existing European networks in this area .

- The NCIPD *started the organization of a new BSL 3 laboratory for identification of very dangerous viral pathogens* as a part of our activity in implementation of the provisions of BWC with the substantial help of the USAID and ANMRO / American Navy Medical Research Office – Cairo, Egypt / .

- Since 1971 *a special State Regulation issued by the Ministry of Health strictly and in details orders the requirements about the premises, the equipment and the staff working with dangerous bacterial and viral agents.* This document is modified and ameliorated during the years according the contemporary achievements of the science and the current practice. The latest version of this order was made three years ago and now it is a very comprehensive document clearly determines the all obligatory requirements for laboratory work with dangerous pathogens / level III and IV / according *the good laboratory practice* and the guidelines of the WHO in this field

- *A notification reporting system for 65 infectious diseases* determined at the national level exists since 1952. The information for any kind of infectious diseases : natural occurring cases, outbreaks, epidemics or cases of alleged use of biological or toxin weapons and suspicious outbreaks is coming from so called “first level” sources that means from: physicians in urban and rural level, GPs, Hospitals, Health Centers, Private Physicians who are obliged according to the law immediately to inform the district RIPCPH, the National Center of Infectious and Parasitic Diseases and the Ministry of Health.

- In Bulgaria we have more than 250 microbiological, virological and parasitological laboratories in public and private sectors working in diagnostic or research field. All these laboratories are under constant control and monitoring on the basis of *the National System for Accreditation, QC and QA.* This activity is organized and performed by a special body, which consists of a group of the best professionals in the country in the above mentioned specialities – the so called *National Consultants* appointed by the Minister of Health. This body, on the basis of *the National Reference Laboratories* for different pathogens, which belong to the *National Centre of Infectious and Parasitic Diseases (NCIPD)* in Sofia, practically forms the *National Review Body* overseeing the quality of diagnosis, potentially dangerous activities, risk factors, licensing the laboratories, organizing the training and licensing the personnel, etc., and has all the information about the work carried out in them

- All laboratories are obliged to carry out their work according to officially approved by the Ministry of Health *National Standards for microbiology, virology, parasitology*. They actually represent a kind of Constitutions for them and a base for performing of the activities in these medical specialities according requirements of the GLP (Good Laboratory Practice), biosafety and biosecurity .According to the National System for Accreditation, QC and QA all laboratories in Bulgaria are obliged to take part twice of a year in this control mechanism in order to receive a special certificate giving them the right to continue to work and to sign a contract with the National Health Insurance System.

- Our *National Reference Laboratories* from 1997 are under constant external/international quality control by WHO / European Office /, INSTANT / Germany /, CEQUALL / Germany / and have international accreditation on the base of *EN/ISO/IEC 17025:2001*. In terms of the quality of diagnostic work, biosafety and biosecurity in our laboratories helps us very much also that the National Center of Infectious and Parasitic Diseases has full membership at CLSI / USA / from 1997 what allows us to have full access to the most contemporary laboratory standards and to implement them in our practice.

- *The Department for epidemiology and surveillance of communicable diseases to NCIPD* integrates and analyzes the whole information in the field of infectious diseases, develops intensive international relationships for exchange of information being an active member of the different international networks for surveillance and early warning.

- Having in mind the anthrax bioterrorism attacks *in 2001* our government funded the construction and equipment of *a new biosafety level III laboratory for very dangerous bacterial pathogens*. Very well trained specialists: medical doctors, biologists, technical assistants are working in this laboratory and we may rely on them in case of natural or intentionally provoked infectious diseases like anthrax, tularemia, brucellosis, hemorrhagic fever, cholera, legionella disease etc.

- We settled a very *active and productive collaboration with ECDC* by participating in different twinning projects, educational courses, workshops etc. for strengthening the capacity of our health system for effective surveillance and organization of modern computerized network for reporting of communicable diseases, including HIV/AIDS and tuberculosis. *NCIPD is designated by ECDC as a "National competent body"* in surveillance of infectious diseases.

- As a result of these activities our *National Center of Infectious and Parasitic Diseases /NCIPD/* has been designated in 2006 as a *WHO Collaborating Center for research and training in surveillance of communicable diseases and antimicrobial resistance*. One of our main tasks will be the coordination and a close collaboration in the above mentioned fields with Southeast European countries and some North African countries. It will allow us to work very actively in implementation of the provisions of the Convention, to strengthen the international efforts in this respect, to exchange experience and expertise and to create a really effective early warning system for intended and unintended communicable diseases. And finally as a new member of the EU we have to continue to harmonize our legislation and regulatory documents in the field of public health and particularly in infectious disease control with the existing in EU in order to be a relevant and reliable partner in the join efforts to fight bioterrorism