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ANNEX VI

THE EU REFERENCE LABORATORY FOR PUBLIC HEALTH ON DIPHTHERIA AND PERTUSSIS, ITS RESPONSIBILITIES AND TASKS

1. The consortium designated as the EU reference laboratory for public health on diphtheria and pertussis (hereinafter 'EURL'):

Consortium led by:

University of Turku, Yliopistonmäki, 20014 Turku, Finland

Also composed of:

Institut Pasteur, 25-28 rue du Docteur Roux, 75724 Paris Cedex 15, France

Vrije Universiteit Brussel, Pleinlaan 2, 1050 Brussel, Belgium

Sciensano, Juliette Wytsmanstraat 14, 1050 Brussels, Belgium

Bayerisches Landesamt für Gesundheit und Lebensmittelsicherheit, Eggenreuther Weg 43, 91058 Erlangen, Germany

2. Responsibilities and tasks

The EURL shall provide support to national reference laboratories and promote good practice and quality to strengthen public health microbiology in the field of diphtheria and pertussis.

The EURL shall provide support to the members of the laboratory networks of the European Centre for Disease Prevention and Control (ECDC)'s European Diphtheria Surveillance Network (EDSN)[1] and the Pertussis Network on aspects related to diagnostics, testing methods, use of certain tests for the uniform surveillance, notification and reporting of diseases.

For the implementation of the activities under the EURL's work plan which the EURL shall develop and agree with the ECDC, the EURL shall coordinate the laboratory networks of EDSN and the Pertussis Network consisting of the National Focal Points (NFPs) for Vaccine preventable diseases and the Operational Contact Points (OCPs) for Microbiology for diphtheria and for pertussis.

Upon request from the ECDC, the EURL shall participate in relevant ECDC networks and structures. The EURL shall participate in the network of EU reference laboratories that is to be operated and coordinated by the ECDC in accordance with Article 15(3) of Regulation (EU) 2022/2371.

The EURL shall ensure that there is:

[1] https://www.ecdc.europa.eu/en/about-us/partnerships-and-networks/disease-and-laboratory-networks/edsn

- a sufficient number of qualified staff in relation to the volume of the tasks that the EURL is to carry out in their scope of designation;
- adequate training of staff for the execution of the tasks of the EURL.

The EURL shall establish its confidentiality policy, including rules for the appropriate secure handling, storage and processing of samples and information, including measures to prevent undue disclosure of confidential information.

The EURL shall be responsible for the following tasks:

(a) Providing reference methods, such as for diagnostics, antimicrobial susceptibility testing or characterisation purposes in the field of the EURL to members of the network(s) supported by the EURL, according to the needs defined by these network(s);
(b) Providing external quality assessment schemes for diagnostics or characterisation, in the field of the EURL to members of the network(s) supported by the EURL, according to the needs defined by these network(s);
(c) Providing scientific advice and technical assistance, including on diagnostics and characterisation, whole genome sequencing, bioinformatic analyses and genomic typing, genomic typing-based surveillance and other topics related to the field of the EURL to members of the network(s) supported by the EURL, according to the needs defined by these network(s);
(d) Providing scientific advice and technical support to the ECDC on laboratory topics, method developments including genomic typing, material availability and other topics related to the field of the EURL;
(e) Providing scientific and technical assistance to the Commission concerning the EURL's specific area of public health and in coordination with the ECDC;
(f) Performing seroprevalence studies in the field of the EURL;
(g) Performing gap analyses in the field of the EURL, to identify needs/gaps within the EU/EEA and for the members of the network(s) supported by the EURL;
(h) Providing information, guidance and support to the ECDC in outbreak situations in the field of the EURL, including providing contributions to ECDC risk assessments;
(i) Organising and delivering training, including wet lab training, in the field of the EURL to members of the network(s) supported by the EURL;
(j) Organising and delivering twinning visits in the field of the EURL for members of the network(s) supported by the EURL;
(k) Ensuring coordination, communication and dissemination with members of the network(s) supported by the EURL, and with the ECDC;
(l) Organising laboratory network meetings in the field of the EURL;
(m) Ensuring coordination with other EU reference laboratories in public health and/or in other areas such as *in vitro* medical devices, the World Health Organization (WHO) Collaborating Centres or relevant initiatives in the field of the EURL;
(n) Collaborating, in cooperation with the ECDC, with laboratories in third countries and the European Medicines Agency (EMA), as relevant;
(o) Providing scientific and technical assistance on other issues relevant to members of the network(s) supported by the EURL.