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ANNEX I

THE EU REFERENCE LABORATORY FOR PUBLIC HEALTH ON ANTIMICROBIAL RESISTANCE (AMR) IN BACTERIA, ITS RESPONSIBILITIES AND TASKS

1. The consortium designated as the EU reference laboratory for public health on antimicrobial resistance (AMR) in bacteria (hereinafter 'EURL'):

Consortium led by:

Statens Serum Institut, Artillerivej 5, 2300 Kobenhavn S, Denmark

Also composed of:

Danmarks Tekniske Universitet, Anker Engelunds Vej 101, 2800 Kongens Lyngby, Denmark

Clinical Microbiology Region Kronoberg, Central Hospital Växjö, Värendsgatan 7, 351 85 Växjö, Sweden

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 AMR in bacteria, with the exception of AMR issues related to *Salmonella* species, *Campylobacter* species and *Neisseria* gonorrhoeae.

The EURL shall provide support to the members of the laboratory networks of the European Centre for Disease Prevention and Control (ECDC)'s European Antimicrobial Resistance Surveillance Network (EARS-Net)¹ and the European Antimicrobial Resistance Genes Surveillance Network (EURGen-Net)² 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 EARS-Net and EURGen-Net consisting of the National Focal Points (NFPs) for AMR and the Operational Contact Points (OCPs) for Microbiology for the pathogens covered by EARS-Net and EURGen-Net.

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 <u>https://www.ecdc.europa.eu/en/about-us/networks/disease-networks-and-laboratory-networks/ears-net-data</u>

² <u>https://www.ecdc.europa.eu/en/about-us/who-we-work/disease-and-laboratory-networks/EURGen-net</u>

- 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 testing 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 harmonised laboratory methods and protocols for diagnostic and 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);
- (c) Providing physical reference materials 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);
- (d) Providing a repository of reference material resources in the field of the EURL;
- (e) Providing external quality assessments, such as phenotypic or genomic proficiency testing, 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);
- (f) Conducting *ad hoc* surveys in the field of the EURL, according to the needs defined by the network(s) supported by the EURL;
- (g) Providing scientific advice and technical assistance 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);
- (h) Providing scientific and technical assistance to the Commission concerning the EURL's specific area of public health and in coordination with the ECDC;
- (i) Providing assessments of laboratory capacity, developing plans for capacity strengthening and/or supporting capacity building in the field of the EURL, according to the needs defined by the network(s) supported by the EURL;
- (j) Coordinating collaborative research studies in the field of the EURL, according to the needs defined by the network(s) supported by the EURL;
- (k) Providing information on relevant national, Union and international research activities in the field of the EURL, according to the needs defined by these network(s);
- Providing support to national surveillance and/or national and cross-border outbreak investigations in the field of the EURL, according to the needs defined by the network(s) supported by the EURL;
- (m)Providing training, via workshops, webinars, simulation exercises and/or pilot surveillance exercises in the field of the EURL to members of the network(s) supported by the EURL;
- (n) Ensuring coordination, communication and dissemination with members of the network(s) supported by the EURL, and with the ECDC;
- (o) Organising laboratory network meetings in the field of the EURL;
- (p) Ensuring coordination with other EU reference laboratories in public health and/or in other areas such as feed, food and animal health and/or *in vitro* medical devices, the

World Health Organization (WHO) Collaborating Centres or relevant initiatives in the field of the EURL;

- (q) Collaborating, in cooperation with the ECDC, with laboratories in third countries and with the European Food Safety Authority (EFSA) and/or the European Medicines Agency (EMA), as relevant;
- (r) Providing scientific and technical assistance on other issues relevant to members of the network(s) supported by the EURL.