EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

European Network of Centres for Pharmacoepidemiology and Pharmacovigilance

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ENCePP Steering group: Mandate for ENCePP support to COVID-19 activities

Background

The scale, severity and novelty of the COVID-19 pandemic raise many questions on clinical features, risk factors and treatments of COVID-19 infections. This creates unprecedented challenges for the epidemiological and regulatory communities:

- Need for data supporting regulatory decision-making and covering disease epidemiology, risk factors for infection and its severity, safety and effectiveness of treatments repurposed to COVID-19 indication, and in the future safety and effectiveness of new treatments and vaccines; the need for data may involve getting access to specific data sources.
- Need for collaborations to design and perform high quality observational studies with regulatory impact, based on large populations and use of best methodological standards.
- Need for expertise to develop (or identify) and disseminate appropriate methods for the study of COVID-19 medicines-related issues; expertise may be needed in a large variety of domains such as pharmacogenomics, infectious diseases, genetic epidemiology, pharmaco-epidemiology, clinical pharmacology, and pharmacovigilance.

ENCePP currently includes 185 centres, 143 data sources and 26 research networks. It covers a very wide scope of expertise and research activities. ENCePP has therefore the opportunity to take a leadership role to support clinicians and regulatory decision makers to provide care for COVID-19 patients that is based on robust evidence. This document proposes a revised mandate for ENCePP and the ENCePP SG in the context of the COVID-19 pandemic. This role would give ENCePP centres high visibility and recognition as key players in the fight against COVID-19 and for public health protection.

Current mandate of ENCePP

The current mandate of ENCePP is to strengthen the monitoring of the benefit-risk balance of medicinal products in Europe by:

- facilitating the conduct of high quality, multi-centre, independent post-authorisation studies (PAS) with a focus on observational research;

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- bringing together expertise and resources in pharmacoepidemiology and pharmacovigilance across Europe and providing a platform for collaborations;
- developing and maintaining methodological standards and governance principles for research in pharmacovigilance and pharmacoepidemiology.[1]

The role of the ENCePP Steering group is to define and safeguard the objectives and principles of ENCePP and decides on operational tasks of the network.[2]

Strengthened mandate of ENCePP in the context of the COVID pandemic

In the context of the COVID-19 pandemic, to strengthen the capacity of the regulatory network and clinicians to monitor and evaluate the benefit-risk balance of medicinal products used in the pandemic. This mandate will be achieved by strengthening the capacity of ENCePP Centres to:

- facilitate access to high quality data and their analysis to support research and regulatory decisions in relation to the COVID-19 pandemic.
- support collaborations aiming to design and conduct high quality multicentre observational research
- improve regulatory science by promoting use and dissemination of valid and reliable methodologies appropriate to COVID-19.

Implementation of the ENCePP COVID-19 mandate

The implementation of the ENCePP COVID-19 mandate will be steered by the ENCePP Steering Group and the EMA. An ENCePP COVID-19 Response Group will be created to identify, prioritise and implementation actions as regards data access, collaborations, funding, and methodologies.

The activities may include:

- To review protocols and reports of COVID-19 studies posted in the EU PAS Register to analyse research topics and study designs.
- Based on the review of the EU PAS Register, to publish an article/editorial with an overview of the observational research initiated so far, research gaps and priorities to be addressed, study designs and methodological aspects to be reinforced.
- To consider creating an inventory of data sources existing at national level that could be leveraged by ENCePP centres to provide evidence
- To develop/identify and disseminate relevant methodological guidance for PE studies on medicines and vaccines.
- Other activities to be identified.

The ENCePP SG will meet at least on a quarterly basis to review the activities performed by the ENCePP COVID-19 Response Group.

[1] http://www.encepp.eu/structure/index.shtml
[2] http://www.encepp.eu/publications/documents/ENCePPSGMandate.pdf