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DARWIN EU Advisory Board: Mandate

Purpose and Background

This document provides the mandate for the DARWIN EU Advisory Board (the Board).

The Phase II report of the HMA-EMA joint Big Data Task Force outlines ten priority recommendations to evolve data-driven regulation, facilitating the development, authorisation and supervision of medicinal products. The first of these recommendations is to put in place the capability to enable access to and analysis of healthcare data from across the EU to support regulatory decision-making on medicines.

This capability is termed the **D**ata **A**nalysis and **R**eal-**W**orld **I**nterrogation **N**etwork – DARWIN EU.

Mandate

The mandate of the Board is to:

1. Provide strategic advice and recommendations to the project team on the establishment of the DARWIN EU capability and its use of the European Health Data Space.

2. Ensure continued coordination and alignment of the project with relevant European initiatives and policy as well as Member state initiatives.

3. Support two-way communication on DARWIN EU with the EU Regulatory Network, stakeholders and the European Health Data Space.

Membership

- Co-chairmanship: HMA – EMA, nominated by HMA and the EMA Executive Director.
- Two representatives of the European Commission[1].
- A representative of at least three and a maximum of five National Competent Authorities following a call for interest from the HMA.
- A representative of an EU payer association.
- A representative of an HTA body.
- Representatives from the already established data permit authorities in France, Finland and Denmark.
- A representative from the Joint Action TEHDAS (Towards the European Health Data Space).
- A representative from the European Centre for Disease Prevention and Control agency (ECDC).
- One representative of EU Patient associations and one of EU healthcare professional associations[2].
- Two representatives from the EMA project team.
- An observer representing the European pharmaceutical industry.

The appointment of the Board will be for an initial period of two-years.

[1] Commission representation will focus on ensuring coordination and alignment towards Commission goals and alignment with the European Health Data Space.
[2] Patient and healthcare professional representatives will be nominated through the EMA Patients and Consumers Working Party and Healthcare Professionals Working Party.

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Board organisation and administrative support

- The Board will meet through teleconference.
- The Board will meet bi-monthly.
- Administrative support including the proposal of meeting dates, the preparation of agendas and the drafting of minutes will be provided by EMA. EMA will normally draft proposals, plans and reports for the Board to consider.
- When needed to progress its work:
  - The Board may request input from other committees, working parties, groups and subject matter experts.
  - The Board may hear representations from stakeholder groups.

Reporting

- The Board minutes will be presented routinely to the Big Data Steering Group.
- The EMA will report on the progress of the DARWIN EU project including recommendations and direction put forward by the Advisory Board at least every 6-months to HMA and the EMA Management Board.

Review

This mandate and composition shall be reviewed on a yearly basis and updated, as needed, based on evolution in data-driven regulation and on the DARWIN EU project progress, until closure of the project (with full operation of DARWIN EU).