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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 (2022-2025 workplan) outlines eleven 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 on the establishment and operation of the DARWIN EU® capability and its use of the European Health Data Space.

2. Ensure continued coordination and alignment 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 Management Group 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.
- A representative of an HTA body.
- Three representatives from the already established data permit authorities.
- A representative from the Joint Action TEHDAS (Towards the European Health Data Space) or any relevant follow on collaboration related to EHDS preparation.
- 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 team.

[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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- An observer representing the European pharmaceutical industry.

The appointment of the Board will be for a renewable period of two years.

Board organisation and administrative support

- The Board will meet through teleconference (a face-to-face meeting may be considered when necessary).
- The Board is expected to normally meet four times per year.
- 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.
  - The Board may invite input from the DARWIN EU® Coordination Centre.

Reporting

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

Review

This mandate and composition shall be reviewed regularly and updated, as needed, based on evolution in data-driven regulation and on the progress of DARWIN EU® until full operation.