EUROPEAN COMMISSION
Directorate-General Health and Food Safety

Directorate C: Digital, Eu4Health and Health systems modernisation

SUBGROUP FOR THE DEVELOPMENT OF METHODOLOGICAL AND PROCEDURAL GUIDANCE

TERMS OF REFERENCE

1. BACKGROUND

Article 3 of Regulation (EU) 2021/2282 establishes the Member State Coordination Group on Health Technology Assessment ("the HTACG"). In accordance with Article 3(7)(k), the HTACG shall establish subgroups.

2. SUBJECT MATTER

The subgroup for the development of methodological and procedural guidance (**"**the Subgroup**"**) is set up. The Subgroup shall operate on the basis of these Terms of Reference, in compliance with Regulation (EU) 2021/2282 and the Rules of Procedure of the HTACG.

3. TASKS

The Subgroup's tasks shall be:

(a) to assist the HTACG in the preparation and update of methodological and procedural guidance on the joint work provided for in Regulation (EU) 2021/2282, including ensuring that it is of the highest quality, follows international standards of evidence-based medicine, is delivered in a timely manner, and is systematically reviewed.

(b) to assist the HTACG in the adaptation of the methodological and procedural guidance to include the specificities of the health technologies to which the joint work relates.

(c) to assist the HTACG in the preparation of its annual work programme and annual report pursuant to Article 6 of Regulation (EU) 2021/2282.

(d) to assist the HTACG in establishing and regularly reviewing standard operating procedures falling within the scope of Article 3(7), points (d), (e), (f) and (g) of Regulation (EU) 2021/2282.

(e) to establish a process to agree on the outputs of the Subgroup.

(f) to assist and coordinate closely with the subgroup for joint clinical assessments, the subgroup for joint scientific consultations, and the subgroup for the identification of emerging health technologies on methodological and procedural issues, guaranteeing scientific consistency and coherence in the performance of their tasks.

(g) to assist the HTACG in establishing cooperation with relevant Union level bodies pursuant to Regulations (EC) No 726/2004, (EU) 2017/745 and (EU) 2017/746 on questions relating to the implementation of Union legislation in the field of health technology assessment, including on facilitating the generation of additional evidence necessary for the joint work.

(h) to bring about an exchange of experience and good practice in the field of methodological and procedural guidance for health technology assessment.

4. OPERATION

1. The Subgroup shall provide regular updates to the HTACG and its Chair and co-Chairs, after each meeting.

2. To ensure scientific consistency and coherence, regular exchanges should be established between the Chairs and co-Chairs of the Subgroup and the Chair and co-Chairs of the HTACG.

3. Meetings of the Subgroup shall, in principle, be held on Commission premises. Meetings may also be held virtually or in a hybrid mode, as provided for in Article 4(5) of the HTACG Rules of procedure. A regular meeting schedule shall be adopted.

4. The Commission shall act as the secretariat of the Subgroup.

5. Summary minutes on the discussion on each point on the agenda shall be meaningful and complete. Summary minutes shall be drafted by the secretariat under the responsibility of the Chair and Co-Chairs of the sub-group.

5. TRANSPARENCY, CONFLICT OF INTEREST AND PROFESSIONAL SECRECY

The representatives appointed to the Subgroup, as well as invited patients, clinical experts, other experts and observers, are subject to the rules on transparency and conflict of interest as set out in Regulation (EU) 2021/2282 and in the general procedural rules to be adopted in accordance with Article 25(1)(a) thereof.

The members of the Subgroup and their representatives, as well as invited patients, clinical experts, other experts and observers, are subject to the requirement of professional secrecy, even after their duties have ceased, as set out in Regulation (EU) 2021/2282 Should they fail to respect these obligations, the Commission may take all appropriate measures.

Done in Brussels, on 20 March 2023.