Brussels SANTE.D.3

Subject: Analyses on markets of medical devices and of medicinal products – MedPro I

(HADEA/2024/OP/0029 (1))

Dear Sir, / Dear Madam,

The European Commission's Directorate-General for Health and Food Safety (DG SANTE) - through the European Health and Digital Executive Agency (HaDEA) - has commissioned a study on "Analyses on markets of medical devices and of medicinal products – MedPro I".

The study, which started on 3 June 2025 and will end on 16 December 2025, has been contracted to a consortium led by Technopolis, in collaboration with the Austrian National Public Health Institute (Gesundheit Österreich Beratungs GmbH/GÖ B), IQVIA and PredictBy.

Under Sub-Task 1.1, which is led by the Austrian National Public Health Institute, the study team will conduct an analysis of the medical device supply chain and shortage management in the EU. The analysis involves defining medical device availability issues and shortages, mapping supply chain dependencies on third countries, and analysing root causes of shortages with a focus on industrial/non-regulatory factors. The study team will examine existing governance structures at the EU level and in other jurisdictions for managing shortages and will develop a methodology for identifying critical medical devices. Based on the evidence, solutions to enhance supply chain resilience will be proposed and their feasibility and impact will be analysed. This analysis aims to support ongoing efforts to address medical device availability challenges in the EU.

To conduct the study appropriately, the study team will approach stakeholders (e.g. regulatory authorities, industry representatives, healthcare providers) for several consultation activities, including interviews, a survey and a workshop. This consultation is a key source of information for the assignment, and we kindly invite you to assist the study team to provide input. Thank you in advance for your valued cooperation.

Acting in full compliance with EU competition law, and within its limits, the study team will keep any specific information (raw data) collected at the individual level **strictly confidential** and under no circumstances will individualised information be disclosed. The study team will ensure that the data is handled with the utmost care and protection. Only **aggregated survey outcomes will be published and included in the final reports**.

⁽¹⁾ Specific contract No HADEA/2025/SC/0022 implementing framework contract No SANTE/2024/OP/0029

Should you have any questions, please do not hesitate to contact <u>SANTE-MED-DEV@ec.europa.eu</u>, and/or the study team (<u>medical.devices@goeg.at</u>).

Yours faithfully,

(Electronically signed)

Flora Giorgio Head of Unit