19 December 2025

Ref: MMA/MDPCED-003/2025

Notice to Stakeholders – European Commission (EC) Communication

On 16 December 2025, the European Commission proposed a targeted simplification of the current rules for medical devices to make them easier, faster and more effective, and to further promote competitiveness, innovation and a high level of patient safety in this key sector. The proposal will simplify EU rules for medical devices, support the digitalisation of procedures, and offer a modern, adaptive framework so that companies can respond to changing market conditions and patient needs.

Stakeholders are advised to regularly visit the Medical Devices webpage on the Medicines Authority website for any updates related to medical device regulatory sciences: https://medicinesauthority.gov.mt/medicaldevices.

Kindly note that a new page entitled "European Commission (EC) Communication" has been introduced. Clarification requests may be forwarded to the general medical devices mailbox: devices.medicinesauthority@gov.mt.

Yours sincerely,

Medical Device Vigilance and Surveillance Unit
Medical Devices, Pharmaceutical Collaboration and Entrepreneurship Directorate

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