EU a step closer to adopt Expansive New Rules Covering Batteries for Medical Devices

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The EU will introduce a major new regulation on batteries, including those used in medical devices. This "cradle-to-grave" regulation will impose new obligations on each step in the lifecycle of a battery, from extraction of raw materials through to disposal.

The EU's proposed legislation aims to promote a circular supply chain, with key obligations including supply chain due diligence; a maximum carbon footprint; minimum recycled content; recycling efficiency levels; performance, replaceability, reporting, and labeling requirements; extended producer responsibility for collection and recycling used batteries; and a digital battery "passport" to capture key lifetime events.

The proposed regulation is expected to be adopted in late 2022 or early 2023. Stakeholders that operate in the EU market for medical technologies should be alert for developments and prepare for the new regime by reviewing their supply chains and operations.

1. Background to the proposal

The proposal is part of the EU's Green Deal, a sweeping packaging of environmental legislation that aims to achieve climate neutrality by 2050, to reduce biodiversity loss, and to promote circularity in the economy.

The EU Commission's proposal was tabled in December 2020 and is now moving at pace through the EU's legislative process. The various branches are broadly aligned on the need for an updated regulation. However, the EU Parliament favors more far-reaching requirements, whereas the Council is seeking to dial back some aspects. To hash out the final text, the EU Council and Parliament began joint discussions in May 2022.

The proposed regulation imposes a detailed matrix of obligations, covering the following types of batteries: portable, industrial, automotive, and electric vehicle (EV). The precise obligations differ according to type. Medical devices typically use portable batteries, comprising a broad, catch-all category, defined in the regulation as sealed batteries weighing less than 5 kg, which are *not* designed for industrial purposes and are *not* EV or automotive batteries. Also potentially relevant to medical devices are industrial batteries, defined as batteries designed for industrial use, and any other battery that is not a portable, EV, or automotive battery. This note focuses on obligations applicable to these two categories.

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2. Key obligations

The proposed obligations affect the full lifecycle of batteries, including: "upstream" requirements on the sustainable production, related labeling and information, and "downstream" requirements on end-of-life management. Main obligations apply to producers that make a battery available on the EU market (separately or integrated in an appliance), with additional obligations layered onto other actors in the supply chain. Producers may exercise their responsibilities individually or collectively through certain organisations.

a. Upstream sustainability requirements on production

The proposal requires batteries to meet sustainability and safety criteria in order to access the EU market. The key requirements (not exhaustive) are set out below. Unless a date is specifically provided, the implementation date is not yet settled; the Parliament sets the date six months from entry into force, while the Council suggests 12 months from that point.

- Prohibition on hazardous substances: *Portable batteries* must not contain any listed hazardous substance (list can be expanded over time).

- Carbon footprint requirements: *Rechargeable industrial batteries* must be accompanied by a carbon footprint declaration (as of July 1, 2024); from January 1, 2026, bear a label indicating the carbon footprint class; and from July 1, 2027, meet a maximum carbon footprint threshold.

- Recycled content: *Industrial batteries* are subject to the requirements below (the Parliament proposes to extend these requirements to certain *portable batteries*):

    - From January 1, 2027, batteries must be accompanied by documentation indicating their contained amount (if any) of cobalt, lead, lithium, or nickel that is recovered from waste.

    - As of January 1, 2030, batteries must contain a minimum share of recycled materials, specifically 12% cobalt, 85% lead, 4% lithium, and 4% nickel.

    - As of January 1, 2035, their minimum recycled content increases to 20% cobalt, 10% lithium, and 12% nickel (lead remains at 85%).

- Performance and durability requirements: *Portable batteries of general use* (specifically formats 4.5 volts (3R12), D, C, AA, AAA, AAAA, A23, 9 volts

(PP3)) and *rechargeable industrial batteries* must meet minimum performance and durability standards as of January 1, 2027.

  - Specific requirements will be determined for each category by delegated act, which the Commission must adopt by December 31, 2025, for portable batteries and by December 31, 2024 for industrial batteries.

  - In addition, by the end of 2030, the Commission is set to assess the feasibility of phasing out non-rechargeable portable batteries of general use. The Parliament has suggested setting the deadline at the end of 2027.

- Removability and replaceability: Appliances using *portable batteries* must be designed so that batteries are "readily removable and replaceable" during, or at the latest at the end of, the appliance's lifetime.

  - Specifically, after the battery's removal from the appliance, it must be possible to substitute the battery by a similar battery, without affecting the functioning or performance of the appliance.

  - The Commission has proposed for this rule not to apply if the continuity of power supply and a permanent connection is required for medical reasons. By contrast, the Parliament has proposed that this exception apply only if there is no alternative available on the market.

- Labeling: *Portable* and *industrial batteries* must bear a "separate collection" label (as of July 1, 2023) and various other labels (as of January 1, 2027) providing information on the main characteristics of the battery, such as lifetime and safety risks; for *portable batteries*, such labels must address capacity and duration.

- QR code: *Portable* and *industrial batteries* must bear a QR code to provide access to (i) all labeling information, (ii) information on the carbon footprint and recycled content, and (iii) a declaration of conformity with the sustainability and safety requirements.

- Battery passport: *Industrial batteries* must be accompanied by an electronic record that will be available through a unique identifier — possibly to be included in the QR code at the Parliament's suggestion. The passport will be linked to information on basic characteristics, performance and durability.

- Due diligence: *Rechargeable industrial batteries'* supply chains must operate under a third-party verified system of control and transparency, based on international due diligence standards (with no agreement yet among the institutions on which standard(s) to apply). Due diligence requirements serve to identify, assess, and mitigate adverse effects of the supply chain, related to specific raw materials and concerning a list of social and environmental risk categories. The Parliament and the Council advocate for a more comprehensive list of risk categories; the Parliament further wishes to expand the list of raw materials and to introduce a liability regime.

b. Downstream requirements on end-of-life management of batteries

The proposal also regulates the end-of-life stage in the life of a battery, including requirements on the collection, treatment, and recycling of waste batteries. These include:

- Extended producer responsibility (EPR): Producers of *portable* and *industrial batteries* are responsible for waste management of batteries. The obligation is applicable in the EU Member State where the battery was first made available.

    - Producers of *portable batteries* must establish (and pay for) suitable collection points, and maintain *minimum collection targets*, calculated as percentages of portable batteries they made available for the first time in a Member State. The Commission has suggested an initial collection rate of 45% by the end of 2023, which would rise to 65% by the end of 2025 and to 70% by the end of 2030. While the Parliament suggests more ambitious targets, the Council advocates for later end dates. The same minimum collection requirements apply at a country level.

    - Producers of *industrial batteries* must take back *in full*, and free of charge, waste of batteries they have made available on the specific EU Member State market and establish (and pay for) accessible collection points.

- End-of-life information: Producers of *portable* and *industrial batteries* must make available, to end users and distributors, information on the management of waste batteries, such as the separate collection and available reuse/recycling systems, safety instructions, and the effect of certain substances as well as the meaning of labels and symbols that the batteries will bear.

- Recycling: Waste *portable* and *industrial batteries* must be collected and recycled, with the recycling process meeting (i) minimum efficiency standards

and (ii) minimum recovery levels of cobalt, copper, lead, lithium, and nickel. The precise targets and their timelines are yet to be agreed, with the Parliament pushing for more demanding targets than the Commission and the Council supporting slower phase-in.

Recycling outside the EU: Waste *portable* and *industrial batteries* may satisfy the recycling targets (as presented above) when exported from the EU but only if the exporter can affirmatively prove that the treatment took place in conditions that are equivalent to the requirements of the Regulation. The Parliament has proposed a higher standard, requiring that the exporter provide "documentary evidence approved by the competent authority of destination" that the relevant requirements are met; the Parliament additionally seeks compliance with relevant environmental and human health protection requirements in other EU legislation.

3. Specific considerations for the medical technology industry

For the medical technology industry, these new regulations run parallel to existing and rigorous patient safety and performance requirements.

Given the added complexity, the industry has advocated for a lengthier transition period (especially for new design-related requirements) in order to validate the performance of newly designed batteries and appliances and make necessary adjustments. Additionally, with respect to general recycling requirements, the industry has warned these may not be easily transposable to batteries intended for single-use medical devices, which may carry health hazard risks. Finally, the proposal envisages complete phase out of non-rechargeable portable batteries. Again, this may pose a particular challenge for batteries used in medical devices — rechargeable batteries require more extensive device management, and have a shorter life, potentially giving rise to concerns over patient safety and product performance.

The EU has already tabled some exceptions for batteries used in medical devices, and it may be appropriate to push for more flexibilities to ensure a feasible application of the proposed regulation and balance with patient safety.