

Circular Economy requires innovation – also from policymakers.

Research-based pharma will implement innovative ideas to booster the full potential of the circular economy act for its sector. But this will require policies which enable an attractive market for circular products in the EU.

Executive Summary

Following the recommendations from the Draghi report and the targets defined in the Clean Industrial Deal and the Competitiveness Compass, the Circular Economy Act aims to accelerate the transition to a more circular economy inside the European Union. The Act will establish a single market to facilitate free movement of 'circular' products, secondary raw materials and waste to increase the economic security, resilience, competitiveness and decarbonisation of the EU.

The vfa and its members of research-based pharmaceutical industry support the European Commission's ambition to strengthen the EU's circular economy activities to reach the 2050 climate goals. Circular economy will help to significantly reduce Europe's overall CO₂-footprint and will furthermore provide options to reduce dependencies on non-EU sources for primary raw materials.

The development and manufacturing of pharmaceutical products for human use is heavily regulated by legislations and guidelines to strictly ensure the quality and safety of the products. Therefore, the use of secondary raw materials in pharmaceutical manufacturing needs to be considered carefully.

However, many components from used or unused medicinal products are of very high quality and

could be valuable as secondary raw materials for other sectors. But since waste from medicinal products is mostly classified as hazardous waste, these components are hardly usable for re-circularization, neither for the pharma-sector itself nor even for other sectors.

Key Messages

- **Ensure patient safety while enabling innovation** – during development and use of medicinal products, circular economy measures must align with stringent pharmaceutical regulations to ensure quality and safety of the products as well as to prevent counterfeiting and misuse.
- **Remove market and regulatory barriers** – harmonized EU rules are essential for scale and competitiveness, especially in member states with federal substructures.
- **Leverage research-based innovation** – Europe can lead if the framework supports R&D investment in circular solutions.

Pharmaceutical products are essential for public health and subject to stringent EU and global regulations (GMP, GDP, pharmacovigilance). These standards must guide the design of circular

economy policies to ensure that safety and efficacy of medicinal products are never compromised. Therefore, the use of secondary raw materials in pharmaceutical manufacturing is related to multiple very specific challenges including:

- Risk of contamination from recycled content especially in primary packaging.
- Complexities in medical e-waste recycling (biosafety, data protection).
- Divergent national rules increase compliance burdens.
- Prohibition of cross-border shipment of medical waste currently prevents efficient use of recycling capacity across the EU
- Diverging or overly rigid obligations under separate legislative frameworks (e.g., CEA vs. PPWR) risk creating conflicting requirements for pharmaceutical packaging and undermining harmonization efforts

For research-based pharma companies, this means that moving into a more extensive circular economy must also be compatible with their targeted R&D pipelines and the very stringent regulatory requirements for this sector, with high product quality and long product life cycles.

Policy Recommendations

- 1.** Until today, most components of unused and used medicinal products are considered as hazardous waste and cannot enter circularity but need final disposal by land filling or burning. However, these waste materials are often still of very high quality and can be used as secondary raw material for products in other sectors.
- 2.** For the establishment of an effective and economically attractive EU-wide circular economy network, cross-border transport of medicinal product-waste into specialized recycling facilities in different member states must be facilitated. Currently, the approval procedure for transboundary shipment notifications within the EU is excessively time-consuming – taking about 6 to 9 month – and valid for only one year. To enable a functional circular economy, this process should be streamlined, for instance by facilitating

the renewal of notifications for identical waste types and transport routes, or by extending the validity period of such approvals. Moreover, harmonizing waste classification across EU member states would significantly simplify and accelerate cross-border waste shipments, thereby supporting the development of specialized, high-efficiency recycling facilities capable of recovering valuable raw materials from medical waste.

- 3.** Mandatory use of recycled materials in pharmaceutical manufacturing and packaging may pose risks to the quality and stability of medicinal products. Subsequently, this may pose risks to patient safety and therefore needs to be considered very carefully.

- 4.** Certain elements and substances in solvents, reactants, intermediates or active pharmaceutical ingredients (APIs) can be used as secondary raw materials or can be re-used directly back into the pharmaceutical manufacturing processes. However, the complex regulation of pharmaceutical manufacturing often blocks circularity of such materials or makes it at least practically and economically unattractive. Therefore, it will be required to establish a union-wide juridical framework to allow collection, transport and re-use of medicinal waste across all EU-member states. Additional local regulations need to be omitted.

- 5.** Complex products such as injection pens, which may contain batteries, circuit boards, and metals, require specialized dismantling and material recovery processes to feed components into appropriate (often non-medical) circular value chains. However, currently the investment in new and innovative recycling methods for the recycling of components from medicinal products is considered as commercially not sufficiently attractive for many recycling companies. Therefore, incentives should be established for research and development of new technological recycling methods.

- 6.** Research in new innovative pharmaceutical-grade material development e.g., mixed-layer blisters consisting of new and recycled materials need to be intensified in line with the adaptation of the applicable regulatory

requirements, if required. If the EU seeks to exploit recycled materials as a decarbonization lever, these recycled materials must be made available at high quality and at more reasonable prices to ensure their broader use in pharmaceutical applications.

7. Furthermore, take-back schemes for certain medicinal products or packaging elements such as e.g., cool-boxes electronic application pens can be established and expanded when properly incentivized. For example, in Sweden the design of take-back schemes for post-used inhalers is hindered by difficulties in transboundary shipments of waste. Larger material volumes with specific characteristics are required to make recycling processes efficient. As the Swedish supply is currently too low to enable domestic high-quality recycling, specialized cross-border hubs could help meet the necessary technological and economic scale requirements

8. It is important to establish harmonized definitions and industry standards for methods and material quality within the circular economy. In this context, regulations and guidelines for circular economy need to be harmonized across the member states, also with requirements outlined in other legislations relevant for this topic. Moreover, promote certification schemes for recycling processes in the pharmaceutical sector to ensure compliance, traceability, and high-quality output.

9. Not all medicinal products are equally suitable to enter circular economy. Therefore, products need to be properly classified for recycling options and regulated accordingly (e.g., narcotics may need to be exempt or specifically handled). When unused medicinal products are entered into circular economy processes, they may need specific storage and transportation requirements to prevent misuse and fraud.

10. It needs to be acknowledged that medicinal products are heavily regulated. Adding additional information to the primary or secondary packaging of medicines about raw materials contained in the product and/or their suggested recycling methods will require regulatory approval. It needs to be a priority that such

additional information (e.g., addition of a new QR-Code) will not confuse patients and will not have any negative impact on the safe use of the medicinal product. At the same time, pharmaceutical regulation should be better aligned with the "reduce" mindset. Current requirements for extensive regulatory text on leaflets and packaging often lead to larger packaging sizes, higher material use, and increased emissions from heavier shipments. Implementing regulatory provisions that enable material reductions such as allowing the use of digital information channels—without compromising patient safety should therefore be considered a top priority. Therefore, apply e.g., Digital Product Passports (DPP) for relevant non-pharmaceutical products in the CEA scope, while exempting medicinal products.

11. It must be ensured that use of secondary raw materials in pharmaceutical production will not have any negative impact on the quality and/or availability of the medicinal products.

12. It is of utmost importance that use or no-use of secondary raw materials for medicinal products will not impact on the physician's or even the patient's decision to use a medicine or not. Medicinal products which cannot enter circular economy still need acceptance of the public for the effective treatment of serious diseases.

Conclusion

The pharmaceutical industry is committed to advancing the EU's circular economy objectives. Research-based pharmaceutical companies are ready to act as strategic partners – bringing together scientific expertise, regulatory experience, and a proven track record of innovation – to ensure that circularity measures both protect patient safety and unlock competitive advantage for the EU. A balanced, risk-based regulatory approach can safeguard health, ensure compliance, and unlock innovation.

With the right regulatory support, the current selected pilots in circular economy in the pharmaceutical industry can be scaled across the

EU, contributing to both environmental and economic goals.

Research-based pharmaceutical companies are uniquely positioned to drive such scaling, leveraging in-house material science, process engineering, and global best practices – but they require stable and predictable rules to justify long-term investment in EU facilities and technologies.

Additional innovation opportunities include research into the recovery and purification of valuable active pharmaceutical ingredients from unused or expired medicines, and reviewing expiry date rules to allow safe, science-based extensions, thereby avoiding unnecessary waste. The pharmaceutical industry stands ready to collaborate with policymakers to co-design workable standards and harmonized frameworks that enable a truly circular, competitive, and secure EU market.

About the vfa

The German Association of Research-Based Pharmaceutical Companies (vfa) represents the interests of more than 40 leading research-based pharmaceutical companies in Germany. Its members are responsible for over half of the German pharmaceutical market by value and invest heavily in research and development of

innovative medicines. The vfa engages with policymakers, regulators, and stakeholders at national and European level to foster a regulatory and market environment that supports innovation, ensures patient safety, and promotes sustainable healthcare systems.