BEUC'S TRILOGUE RECOMMENDATION ON THE PHARMA LEGISLATION

BEUC The European Consumer Organisation

The Consumer Voice in Europe

Why it matters to consumers

Europe faces serious challenges: growing shortages, high prices, and innovation that does not fully match patients' real needs. The EU pharmaceutical legislation's revision comes at a decisive moment, alongside negotiations on the Critical Medicines Act. Both will shape future access to safe, available, and affordable medicines. This reform is a unique chance to improve access, strengthen trust in the regulatory system and healthcare systems' resilience across Member States.

This two-pager sets out BEUC's 6 key recommendations for trilogue negotiations to secure real benefits for consumers and patients. For more information, see our key recommendations, the Commission's proposals (directive & regulation) as well as the Parliament's (directive & regulation) and Council's (directive & regulation) positions.

1 MEDICINES MARKETING AUTHORISATION

The current rules have transparency gaps that can lead to conflicts of interest, lack of consumer understanding, and delays in industry post-marketing obligations for medicines entering the market earlier.

WHY IT MATTERS

Strengthening transparency and accountability will help doctors, patients, and consumers make more informed treatment choices.

It is especially important for:

- Medicines approved conditionally
- Scientific advice

BEUC RECOMMENDATIONS

We support the following **European Parliament's proposals, improving transparency**:

- Requiring the European Medicines Agency (EMA) to publish the list of conditional approvals in its database, with information on the companies' post-marketing obligations timelines, potential delays, reasons, and follow-up actions.
- Embedding the European Ombudsman's suggestions to strengthen transparency, accountability and trust in scientific advice, by preventing conflicts of interest and potential industry misuses.
- The EMA should further enable non-profits (e.g. hospitals producing innovative therapies) to receive scientific advice and promote public discussion on scientific developments and guidelines.

2 MEDICINE PACKAGE LEAFLETS

Paper leaflets are the easiest and, for some patients, the only way to access essential information on safe medicine use.

WHY IT MATTERS

Electronic product information (ePI) offers new opportunities, but it can be hard to access for people with low digital skills or limited internet. It should complement rather than replace paper leaflets.

BEUC RECOMMENDATIONS

We support making paper leaflets and ePI complementary **(Council)** but worry about allowing Member States to remove paper leaflets beyond specific cases. Before moving to digital-only information, authorities should consult patients and doctors **(Parliament)**.

If a pack only comes with ePI, companies must ensure that a free printed leaflet can be available upon request at pharmacy **(Council).**

Regarding personal data protection and e-Privacy, we support the stronger provisions added by the Parliament. We also support preventing the Commission from removing paper leaflets across the EU through a delegated act **(Council and Parliament)**.

BEUC The European Consumer Organisation

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3 INCENTIVES TO INNOVATION

Patents, supplementary protection certificates, and regulatory exclusivity keep medicine prices high and delay generic competition and innovation for too long.

WHY IT MATTERS

This puts public health systems under pressure and creates inequalities in treatment access.

At the same time, we need fair and sustainable ways to develop new antibiotics which must be used carefully to avoid antimicrobial resistance (AMR).

BEUC RECOMMENDATIONS

1. Modulation: adjusting medicines' data protection and market protection lengths depending on their added value for public health

We recommend modulating market protection without exceeding the current 11-year maximum **(Council)**. But this requires that generics companies can apply for market approval sooner than is currently possible.

2. Antimicrobial development:

The use of 'Transferable exclusivity vouchers' (1) to promote antimicrobial development risks delaying access to generics in other areas. It should come with strong safeguards that mitigate negative impacts **(Parliament and Council)**.

We endorse more consumer-friendly pull incentives to innovation, like milestone prizes and a subscription model tied to joint procurement **(Parliament)**.

(1) Vouchers that companies obtain if they produce a priority antimicrobial granting them extra legal protection time for another product.

4 MEDICINE AVAILABILITY ACROSS THE EU

Often, pharmaceutical companies with EMA-approved products do not try to promptly make them available across the EU.

WHY IT MATTERS

This contributes to inequalities in access to essential treatment. The new rules should push companies to make medicines promptly available across the bloc.

BEUC RECOMMENDATIONS

We support combining an obligation for companies to file for pricing and reimbursement upon Member States' request, with a one-year loss of market protection in any country where a new innovative medicine is not available in the end **(Council)**.

We also support publishing the list of countries where a medicine is actually made available in the EMA's database **(EP)**.

5 MEDICINE SHORTAGES

Consumer surveys showed that 40% of households suffered a drug shortage between 2023 and 2024.

WHY IT MATTERS

Shortage prevention is key to help detect risks early and strengthen supply chains, through better demand forecasting and diversified sourcing.

BEUC RECOMMENDATIONS

BEUC is in favour of making industry shortage prevention plans mandatory for all medicines, not only critical ones to maintain continued supplies **(Commission)**.

We further support the following **Parliament's proposals**:

- All Member States should enable consumer shortage reporting and establish a user-friendly public website where consumers can find key information on them (e.g., duration, reasons, therapeutic alternatives).
- Specifying that Union penalties should also cover companies' supply-related obligations, especially those they have towards EU coordination mechanisms.

6 MEDICINE AFFORDABILITY

The public sector's contribution to medicine's research and development (R&D) is key but is often not reflected in the high prices set by pharmaceutical companies.

WHY IT MATTERS

Improving transparency will increase pricing authorities' leverage in their negotiations with industry.

Generics should enter the market as soon as the patent on the originator product expires to make their access timelier.

BEUC RECOMMENDATIONS

BEUC calls for more R&D transparency **(Parliament)** as it ensures a comprehensive overview of the public sector's key contribution (direct and indirect financial support to industry, early research activities).

We support removing all barriers to timely generics market entry **(Council)** (e.g. 'bolar exemption' which allows starting research on generics or biosimilars before a patent expires). We agree this means letting generics companies join hospital tenders, so they can prepare for market entry and provide patients cheaper medicines immediately after a patent expires.