Summary of bilateral meeting: European Medicines Agency and the European Consumer Organisation (BEUC)

10 November 2025, 13:00 -14:00 CET

1. Introduction and tour de table

EMA's Executive Director, the Head of the Stakeholder and Communication Division, and the Head of Public and Stakeholder Engagement department and the patient liaison welcomed the delegates of the European Consumer Organisation (BEUC) to this bilateral meeting.

2. Topics for discussion

BEUC reinforced their commitment to strengthening cooperation with different EU Agencies including EMA, whose work has direct impact on consumers' lives. EMA reiterated the importance of the collaboration with BEUC and the long history of engagement of the consumer organisation in EMA activities.

2.1. Package leaflets and electronic product information

Package leaflets: Concerns about the transition from paper to electronic product information (ePI) were raised by BEUC, in particular accessibility for different segments of the population such as older people or those with limited digital skills. EMA assured that it will be a phased transition to digital formats and will be done in consultation with patients, carers and consumers, to ensure readiness and address their needs. What is best for the patient and consumer is always a high priority.

ePI and QR codes: Questions were raised about the protection of privacy of the user of QR codes and what data is shared. It was clarified that the QR codes will link to an EU repository, not company websites, to mitigate these risks.

2.2. Biotech act and clinical trials

The **Biotech Act** is still open for public consultation, and the proposal is expected in the third quarter of 2026. EMA will continue working with the Commission and involve stakeholders in the implementation process. EMA confirmed that input from patient and consumer organisations will be needed to support the implementation.

Clinical trials: BEUC emphasised that from the consumer perspective, safety is the biggest issue and wants that this continues to be prioritised. While clinical trials remain a national competence, the Biotech Act aims to help member states collaborate more effectively and update outdated regulations to improve competitiveness and patient access. Modernising clinical trials is crucial for maintaining

Europe's competitiveness in research and development, ensuring timely product availability, and gaining valuable European experience with new medicines.

2.3. Medicine shortages

BEUC stressed the importance of transparency of stock levels and emphasised a need for greater coordination across member states.

EMA confirmed that they support more agile stock management, transparency and movement of medicines across countries, which is facilitated by ePI.

EMA has promoted best practices for communication on shortages and observed improvements in member state transparency over the past four years and continues to seek examples and guidance to further enhance communication. Unfortunately, the root cause for the shortage is often not known although the template for the EMA shortage catalogue requires a cause to be completed.

EMA's responsibility for medical device shortages is currently limited to public health emergencies, but the team expressed support for increased coordination and transparency, acknowledging the complexity and differences in the device market.

BEUC is invited to share any ideas on what information would be useful to patients and consumers with EMA.

2.4. Online information on medicines

BEUC highlighted concerns around misinformation and falsified medicines and discussed efforts undertaken by EMA to combat these issues.

EMA is developing a framework to tackle misinformation, focusing on gathering insights through social listening, working with infodemic management experts, and piloting initiatives in the vaccine space. In addition, direct communication strategies to address false claims are being implemented, including dedicated website sections and outreach to younger audiences via social media, podcasts and influencer campaigns.

EMA also collaborates with national agencies to address these issues and communication campaigns are coordinated across the network.

2.5. Medical devices

BEUC wanted to discuss and better understand the role of EMA in medical devices.

EMA confirmed that the Agency is actively involved in expert panels for medical devices and is piloting initiatives for orphan and breakthrough devices, working closely with the Commission to support regulatory reviews. EMA's role in device shortages is currently limited, with most activities focused on crisis situations. The team highlighted the complexity of the device market and the need to focus resources on areas with the greatest impact.

EMA invited BEUC to reach out as needed to help the situation of consumers.

3. Summary of discussion/next steps

The meeting concluded with a shared sense of having had a constructive discussion, focusing on current and future opportunities for collaboration. It was agreed to maintain regular contact and to implement bilateral meetings as needed to discuss cooperation on specific topics.