

Agreement on the EU pharmaceutical package: an achievement to build on.

In the early hours of the morning on Thursday 11th December, the 4th round of the so-called '[pharma package](#)' triologue, concluded with agreement between the European Parliament (EP) and the Council of the European Union (EU). It constitutes the most ambitious overhaul of pharmaceutical legislation in over a decade, addressing how to enhance access, incentivise innovation and avoid medicine shortages. It also provides specific guidance for the development of new and effective antibiotics and grants new regulatory functions to the European Medicines Agency.

When launched in 2023, the European Commission's [proposal](#) was to hasten access to medicines in Europe, restrain pharmaceutical spending and optimise a cumbersome incentive mechanism for innovation. Discussions and debates around the proposal have been intense and, at times, strident.

During discussions in the parliamentary committees it became evident that pharmaceutical companies sought to use the opportunity to push for an [agenda](#) of monopolies on one side, and lack of transparency in prices and procurement deals on the other. This would entrench the status quo, or create an even more favourable legal and regulatory framework for corporate interests. Fortunately, the resulting [decision](#) from Parliament has put an end to the repeated use of market exclusivities and explicitly acknowledged the need of greater transparency.

Successive EU Presidencies (Belgium, Hungary, Poland and Denmark) have shepherded this dossier as a high priority, both due to domestic factors such as increased healthcare costs, and external factors such as changes in US foreign policy, felt in Brussels-based institutions and across the EU as a whole. The [Draghi report](#) (2024) on European Competitiveness had a significant impact on all policy discussions and legal deliberations. Hence, reform of the pharmaceutical sector would not only be about access for patients but also for governments, about strategic assets, both in economic and political terms. Pharmaceutical industry talk about relocating to former EU strategic allies also weighed heavily in these considerations.

With the pharma package piece of the jigsaw agreed in principle (second reading pending), it is the turn of the next legislative piece related to pharmaceuticals: the [Critical Medicines Act](#) (CMA), hailed as the main legal and administrative tool to combat medicine shortages, has just cleared SANT committee. Meanwhile, the European Commission launched the [Biotech Act proposal](#) intended to support the consolidation of a 'cutting-edge' biomedical research sector within EU. In addition discussions around the [Framework Programme 10](#), which will dictate publicly

funded research for the foreseeable future, are taking gathering pace.

In all these cases there is a tension and need for balance between pressures of private and corporate interest and health needs and public interest. We will continue to work to ensure that the former does not suffocate the latter.