POLITICAL INTELLIGENCE

Guide to the Upcoming EU Pharmaceuticals Package

By Beatriz Solanas Huerta

Introduction

The European Commission is due to publish its long-awaited pharmaceutical package on March 29, which is set to include the revision of the European Union's pharmaceutical legislation, a proposal for the revision of the EU legislation on medicines for children and rare diseases, as well as a Council Recommendation on combating antimicrobial resistance. The planned reforms represent key steps in the implementation of the 2020 Pharmaceutical Strategy for Europe, which aims to improve access to affordable medicines across the EU, foster innovation and security of supply, and help the sector reduce red tape and adapt to new scientific developments.

However, the European Parliament and Council will need to work quickly to progress the comprehensive package to avoid it being delayed by parliamentary elections in 2024. Some political groups and stakeholders have voiced concerns that the proposals could make European drug makers less competitive, while others have called for the package to help make drugs more affordable and accessible. EU health ministers have agreed the proposals are a priority, but some member states have called for a focus on making medicines more accessible across the bloc, while others have pushed for innovation of drugs to tackle unmet medical needs or protecting intellectual property rights.

This Dods EU Political Intelligence report provides a one-stop guide to the forthcoming pharmaceutical package, including a preview of the expected Commission measures and next steps, and a selection of views from political groups and stakeholders, including links to original sources. The report also lists key policymakers involved in the reforms.

Preview of the pharmaceutical package

Not long after Stella Kyriakides became Health Commissioner, Commission President Ursula von der Leyen tasked her with developing a regulatory framework that would ensure Europe had an adequate supply of affordable medicines to meet its needs and to "support the European pharmaceutical industry to ensure that it remains an innovator and world leader". In a speech at an Employment, Social Policy, Health and Consumer Affairs (EPSCO) Council meeting of ministers in December 2022, Kyriakides said reforming the EU's pharmaceutical legislation was a priority of her mandate and reiterated the Commission's five key aims:

- Promote innovation, in particular for unmet medical needs
- Create a balanced system for pharmaceuticals in the EU that promotes affordability and rewards innovation
- Ensure access to innovative and established medicines for patients, with special attention to enhancing security of supply across the EU
- Reduce the environmental impact of the pharmaceutical product lifecycle
- Reduce the regulatory burden and provide a flexible regulatory framework

The Commission is expected to propose a new regulation and a directive. The new regulation will replace the authorisation of medicinal products and the establishment of the European Medicines Agency regulation and incorporate and amend the orphan medical products Regulation and the paediatric medicines regulation. The new directive will replace the medicinal products for human use directive.

The Commission is expected to propose numerous changes to the pharmaceutical legislation, including amendments to the system of protection for companies against unbranded competition.

This includes a carrot and stick approach to encourage the pharmaceutical industry to launch new products across the EU27, develop new medicines and antibiotics, and engage in comparative clinical trials. The new proposals are expected to reduce the length of regulatory data protection to six years, but offer potential steps to increase it to a maximum of eight. The Commission is expected to propose an additional year of regulatory data protection for drugs that are made available across the bloc. In addition, the Commission is expected to offer a further year of regulatory data protection for drugs that tackle unmet medical needs. Companies that provide data from comparative clinical trials as part of the registration process could also benefit from an extra six months of regulatory data protection. Another year of protection could be offered to companies for any drug in their portfolio if they develop a new antibiotic that meets certain criteria, the so-called transferrable exclusivity vouchers.

To improve the regulatory approval processes in the EU, the Commission is expected to propose a reorganisation of the European Medicines Agency to reduce duplication of work and simplify procedures. It is also expected to set out plans for a temporary emergency marketing authorisation tool that would allow the EMA to recommend the use of a product during an emergency based on potentially less rigorous than usual efficacy and safety data. The Commission is also expected to present proposals to simplify compulsory licencing systems by suspending data and market protection when a compulsory licence has been issued.

To tackle supply issues for medicines, the Commission is believed to be considering the creation of a monitoring system that would include asking pharmaceutical companies to create shortage prevention plans and also to forewarn member states of temporary supply disruptions, as well as other notification requirements, including when a company plans to exit a market. The Commission is also planning to draw up a list of critical medicines and shortages.

Next Steps

In line with usual procedure, once the Commission has presented its two legislative proposals they will be subject to the ordinary legislative procedure, meaning that the co-legislators (the European Parliament and Council) will work separately to formulate on their respective positions on the package. In the Parliament, work will be led by the Committee on the Environment, Public Health and Food Safety (ENVI), with likely input from other committees including the Committee on Industry, Research and Energy and the Legal Affairs Committee. It remains to be seen whether the newly created ENVI Sub-Committee on Public Health will play a role. In the Council, the Working Party on Pharmaceuticals and Medical Devices will take up the baton with the Employment, Social Policy, Health and Consumer Affairs (EPSCO) Council taking responsibility for the file. EU health ministers are likely to get an opportunity to discuss the proposals at an informal Health Council in Stockholm on May 4-5, though initial discussions may take place at working party level before then.

Once the two legislative bodies have established their respective positions on the pharmaceutical package, they will begin trilogue negotiations with the Commission to agree a final text. The timeline is likely to depend on how quickly the Parliament organise its response, including choosing rapporteurs. Recent reports suggest Peter Liese (EPP, DE) and Stelios Kympouropoulos (EPP, EL) are amongst those vying for the roles. Barring any delays, the Parliament may be able to hold initial Committee discussions before the summer break, which would leave debate on the draft reports and any potential amendments for the autumn period. On that trajectory, a committee vote on the draft reports could take place in early 2024, but the size of the legislative proposals suggests that could be ambitious. However, if the process takes much longer the

reforms risk being disrupted by the parliament elections in May 2024, which could mean the pharmaceutical package is shelved until the new parliament is up and running in September 2024 with further potential delays if new rapporteurs need to be chosen.

Views

European Parliament

The European Parliament set out its view of the EU pharmaceutical strategy in late 2021 when it adopted a non-legislative report written by Spanish centre-right MEP Dolors Montserrat, from the Group of the European People's Party. The report, which was backed by a large majority of MEPs, called for steps to address disparities in the quality of health services both within and between member states and ensure universal and timely access to affordable, effective, and innovative medicines. The MEPs also urged the Commission to assess, and revise where appropriate, the system of incentives to promote research and development of new medicines for unmet diagnostic and therapeutic needs, including for paediatric cancers, rare diseases and neurodegenerative diseases. The report called for "a reimbursement system that favours meaningful innovation for patients and incentivises fewer 'me-too' pharmaceuticals which have no added value or highly expensive pharmaceuticals that offer only minor improvements for patients".

The parliamentarians called for member states to share information on net medicine prices through the European Integrated Price Information Database (Euripid) and enhance transparency of drug research, development, and production. They also suggested the creation of a joint EU fund, co-financed by member states, for negotiating and purchasing new or so-called orphan medicines, which are produced to respond to rare serious conditions or are unlikely to generate enough profit to justify research and development costs. The MEPs also stressed the importance of access to generic, biosimilar and value-added medicines, particularly after intellectual property rights on drugs expire by ensuring access to biosimilar medicines from day one and removing all barriers to access to competition.

The Parliament also called for measures to address the differences in the average number of days between the approval of a medicine and the moment it becomes available to patients in the EU, and implement solutions to reduce delays to the market entry of medicines; reassess the system that leads from conditional marketing authorisation to standard marketing authorisation or exceptional renewal of authorisation, based on robust clinical data; new processes for promoting the repurposing of medicinal products including broader off-label use of medicines, including less expensive medicines and medicines used for rare cancers; and ensure quality and environmental sustainability standards for active pharmaceutical ingredients imported from non-EU countries and address the problem of pharmaceutical household waste, through measures to reduce packaging; and the use of SPCs should be allowed only in exceptional and justified cases.

In October 2022, a group of some 35 MEPs followed up the Parliament report with a joint letter to the European Commission calling for the proposals to focus on steps to boost pharmaceutical research.

Member States

European health ministers were updated on the Commission's objectives and progress on its plans for reforming the EU's pharmaceutical legislation at a Health Council in early December 2022.

They agreed the proposals were a priority for the EU in the wake of the Covid crisis. However, several member states, including Slovenia, Poland, Cyprus and Greece, called for a focus on ensuring that medicines were accessible to all patients across the EU. Some countries, such as the Netherlands, said pharmaceutical innovation to address unmet medical needs should be driven by demand rather than supply and be supported by a graduated system of incentives with additional incentives for products that address unmet medical needs. Italy highlighted the need to work with the pharmaceutical industry and focus on sustainability, guaranteeing intellectual property rights and incentivising research, particularly in relation with rare and paediatric diseases. The Netherlands has also published a non-paper on the revision of the general pharmaceutical legislation calling upon the Commission to "consider further steps or alternative solutions in the areas of unmet medical need, shortage prevention and the environmental footprint of pharmaceuticals".

Stakeholders

The **European Federation of Pharmaceutical Industries and Associations (EFPIA)** said reports of early drafts of the Commission proposals suggested they would undermine pharmaceutical research in Europe. "Whether it is naivety, blind optimism or a more conscious decision for Europe to rely on innovation from the U.S. and Asia, everyone should be in no doubt that what we have seen as draft proposed legislation would be extremely damaging to the competitiveness of Europe's innovative pharma industry and to our region's strategic autonomy. It will have a negative impact on jobs, investment, the European research eco-system, growth, patient access to new clinical trials and availability of the latest treatments for decades to come," EFPIA Director General, Nathalie Moll, said in a statement in February. In a blog post in late January, she had argued that the focus of the proposals must be on reversing the decline of innovation in Europe, claiming "It is our once-in-a-generation chance to reinvent the regulatory framework to ensure we have a modern approach that matches our ambition to be a hub of medical innovation". She called for a "robust and predictable intellectual property framework" and steps to speed up regulatory work including the time taken to approve new active substances.

Medicines for Europe, which represents the European generic, biosimilar and valued added pharmaceutical industries, has called for a new medicine security contract for Europe. In an open letter to European Commissioners, the Swedish Presidency of the Council, and representatives of the European Parliament, the group warned of significant risk of shortages of medicines due to structural causes, including the pricing model for generic medicines in Europe. It called for range of measures, including regulatory flexibility for packaging, discussion of how to counter the impact of inflation, and was to improve supply chai resilience. That followed a statement from a joint event on equitable access to medicines in mid-January which quoted Medicines for Europe Director General Adrian van den Hoven saying inequalities in access to medicine in Europe were unacceptable. "The review of the pharmaceutical legislation this year must focus on strengthening and supporting the off-patent medicines sector, given the value we are delivering for health systems," he said.

EuropaBio has stressed the need to preserve and build upon the stability and predictability of the orphan designation. In a blog on the orphan medicines regulation posted in November 2022, EuropaBio Director General Clair Skentelbery said, "approvals, marketing exclusivity, and regulatory data protection are essential to bring further innovation to market and support the rare disease ecosystem. Incentives are essential to enable the growth and success of smaller companies who use them to raise the necessary funds to continue their pharmaceutical development".

Several associations representing healthcare providers, patients, healthcare professionals and payers, including the **Pharmaceutical Accountability Federation** and **Association of European Cancer Leagues (ECL)**, published a joint statement in late 2022 on the pharmaceutical legislation. They called for the focus to be on fostering affordability to improve access to high-quality medicinal products, improving the assessment and evidence requirement of medicinal products' effectiveness and safety, and ensuring a sufficient supply of medicinal products and combat shortages. The said there should be disclosure of research and development (R&D) costs and the reduction of the duration of exclusivities that impact competition and access. "The EU cannot compromise on safety and quality, even for accelerated procedures".

The Standing Committee of European Doctors (**CPME**) published a position paper on the planned revision urging the EU to restore balance to the pharmaceutical sector in the interest of patients. They called for the Commission to give priority to steps to improve availability and ensure affordability of medicines; ensure more resilient supply chains; review current system of incentives to address unmet medical needs; and ensure safety and quality of medicines.

BEUC, the European Consumer Organisation, responded to the Commission's consultation on the legislative review in 2021, calling for a focus on improving access to medicines across the EU, including improving medicine marketing authorisation methods and ensuring supply. It said pharmaceutical companies should be obliged to develop and submit drug shortage prevention plans to competent authorities and notify authorities earlier of potential shortages. BEUC also called for steps to improve the affordability of medicines by revisiting the intellectual property incentives system and putting in place safeguards to ensure drug affordability and facilitating the introduction of generics and biosimilars on the market. BEUC argued against the introduction of transferable exclusivity vouchers to promote the development of novel antimicrobials pointing out that this would come at a huge cost to health systems, hamper competition and delay patient access to cheaper generics and biosimilars in other disease areas.

The **European Confederation of Pharmaceutical Entrepreneurs (EUCOPE)** published a position paper on the evolution of the EU Regulatory framework and modernisation of the Centralised Procedure in April 2022 with the ambition of faster delivery of novel medicines. Its recommendations included updated and streamlined eligibility criteria and assessment based on most current needs and health care challenges; reduced standard timeline for EMA assessment to 170 days; and a re-consideration of the requirement for a European Commission's decision step. "While updates have occurred over the past 25 years, the revision of the General Pharmaceutical Legislation, as part of the Pharmaceutical Strategy for Europe, presents an opportunity to modernise the procedure and ensure it is fit for purpose and futureproofed for innovative therapies," it said.

The **European Social Insurance Platform (ESIP)** published a response to the public consultation on the revision of EU rules on pharmaceuticals, calling for the focus to be on increasing affordability by strengthening fair competition and revising the framework for incentives. ESIP called for a range of measures, including a common definition of unmet medical needs based on quantifiable criteria and cross-referenced in the EU legislation; revision of the existing framework for incentives, including through measures to avoid misuse of existing incentives; an obligation to place products on the EU27 markets and the introduction of measures at EU level to foster affordability, namely promoting fair competition and honing the joint procurement system. "It is important to strengthen cooperation, by monitoring supply and demand at Member States' level and establishing a common EU monitoring system for shortages,

with reinforced reporting obligations for producers and sanctions in case of non-compliance," it said.

The **Pharmaceutical Group of European Union (PGEU)** published a 12-page position paper in 2022 that said it welcomed the revision of the EU pharmaceutical legislation as a tool to ensure supply of safe and affordable medicines in Europe. It called for the pharmaceutical legislation to improve access and accessibility of drugs; create an adequate regulatory framework which puts the needs of patients at the centre and harnesses the benefits of digital opportunities; and ensure affordability of medicines for patients and health systems financial and fiscal sustainability. "Both the ongoing COVID-19 pandemic and the unacceptable, increasingly negative impact medicine shortages have on patients access to medicines require bold, ambitious, and coordinated actions at all policy levels," it said.

Key Actors
Biographical and contact details are available on the Dods People service. For an example of this, please find links to the biographies of Commissioner Kyriakides and Breton below:

European Commission

- Stella Kyriakides, Commissioner for Health and Food Safety
- Thierry Breton, Commissioner for the Internal Market
- Sandra Gallina**,** Directorate-General for Health and Food Safety
- Olga Solomon, Acting Director for Medical Products and Innovation, DG SANTE
- Giorgos Rossides, Head of Cabinet of Commissioner Stella Kyriakides
- Sylvain Giraud, Head of Unit "Medical products: quality, safety, innovation", DG SANTE

Council of the EU

Sweden holds the rotating six-month Presidency of the Council of the EU until 30 June, followed by Spain and then Belgium at the start of 2024.

- **Jakob Forssmed**, Swedish Minister for Social Affairs and Public Health
- **Acko Ankarberg Johansson**, Swedish Minister for Healthcare
- **Carolina Darias**, Health Minister of Spain

The Swedish Perm Rep to the EU has two Counsellors for Pharmaceuticals:

- **Joakim Svensson**
  Counsellor for Health and Pharmaceuticals
  joakim.svensson@gov.se
- **Andreas Johansson**
  Counsellor for Health and Pharmaceuticals
  andreas.johansson@gov.se.
- **Enrique Terol Garcia**, Spanish Perm Rep for Health

European Parliament

The following MEPs were active in drafting of the EP report on the pharmaceutical strategy:

- Dolors Montserrat (EPP, ES)
- Alessandra Moretti (S&D, IT)
- Tilly Metz (Greens/EFA, LU)
- Simona Baldassarre (ID, IT)
- Andrey Slabakov (ECR, BU)
- Kateřina Konečná (The Left, CZ)

Other MEPs who have participated in questions related to pharmaceuticals include:

- Peter Liese (EPP, DE)
- Deirdre Clune (EPP, IE)
- Stelios Kympouropoulos (EPP, EL)
- Pernille Weiss (EPP, DK)
- Christian Silviu Busoi (EPP, RO)
- Tiemo Wölken (S&D, DE)
- César Luena (S&D, ES)
- Sara Cerdas (S&D, PT)
- Nicolás González Casares (S&D)
- Véronique Trillet-Lenoir (RE, FR)
- Frederique Ries (RE, BE)
- Susana Solís Pérez (RE, ES)
- Jutta Paulus (Greens/EFA, DE)
- Joanna Kopcińska (ECR, PL)
- Marc Botenga (The Left, BE)

Stakeholders

- European Federation of Pharmaceutical Industries and Associations (EFPIA)
- Medicines for Europe
- EuropaBio
- European Association of Hospital Pharmacists (EAHP)

- European Association of Nuclear Medicine (EANM)
- Pharmaceutical Group of European Union (PGEU)
- The Patient Access Partnership (PACT)
- The European Public Health Alliance (EPHA)
- European Hospital and Healthcare Federation (HOPE)
- Standing Committee of European Doctors
- European Confederation of Pharmaceutical Entrepreneurs (EUCOPE)
- European Consumer Organisation (BEUC)
- MEP Interest Group on Equitable Access to Healthcare
- MEPs Interest Group on European Patients' Rights & Cross-Border Healthcare
- AIDES
- Association of European Cancer Leagues (ECL)
- Consilium Scientific
- Global Health Advocates (GHA)
- International Association of Mutual Benefits Societies (AIM)
- NoGracias
- Pharmaceutical Accountability Foundation
- Pharmaceutical Group of the European Union (PGEU)
- Prescrire
- Salud por Derecho
- Standing Committee of European Doctors (CPME)
- The European AIDS Treatment Group (EATG)
- Wemos
- Vaccines Europe
- Innovative medicines initiative
- Innovative health initiative

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