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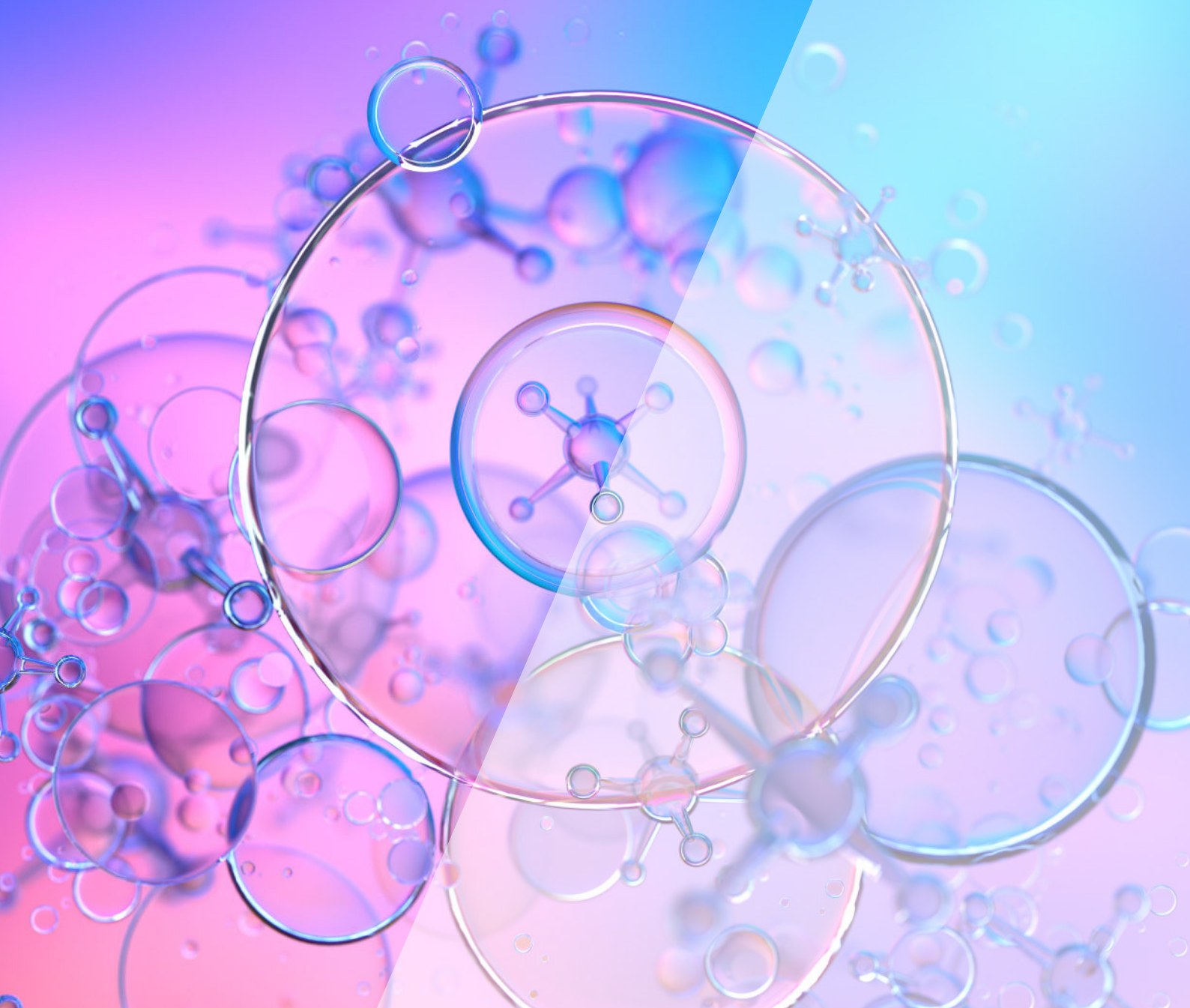
A Decade Defining Moment for Health

A temperature check on the General Pharmaceuticals Legislation in Europe

A report by H/Advisors Public Affairs



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Introduction

Health has moved to the very top of the European Commission's agenda and to the epicentre of policymaking over the last three years, as the COVID-19 pandemic laid bare the urgent imperative to build a resilient and strong European Health Union.

We have seen the strengthening of agencies (ECDC, EMA), the creation of a new authority (HERA), and a range of new actions and goals for digital transformation and global health security. However, with medicines accounting for roughly one-fifth of Europe's health spend, **the major channel through which the EU shapes health systems is invariably via pharmaceutical legislation.** The Commission's November 2020 Pharmaceutical Strategy is a response not only to internal market issues, but also to global competition pressure in the sector.

A key pillar of the Strategy - the highly anticipated legislative proposals overhauling the EU's pharmaceutical legislation - is finally expected to be published in March. The Commission says it is trying to balance a range of interests: equitable access for patients to therapies and cures, the success and competitiveness of industry, the sustainability of national health systems and incentives that encourage research into AMR.

Industry is hoping that the revision of the decades-old legislation will seek to fix long-standing problems, create a first-class, 21st-century regulatory framework that will help reduce regulatory burden, speed up access and ensure Europe is a globally competitive region for medical innovation. Patient advocates are hopeful the legislation will help bring down prices by allowing greater competition across the bloc and by introducing more transparency to the cost of medicines.

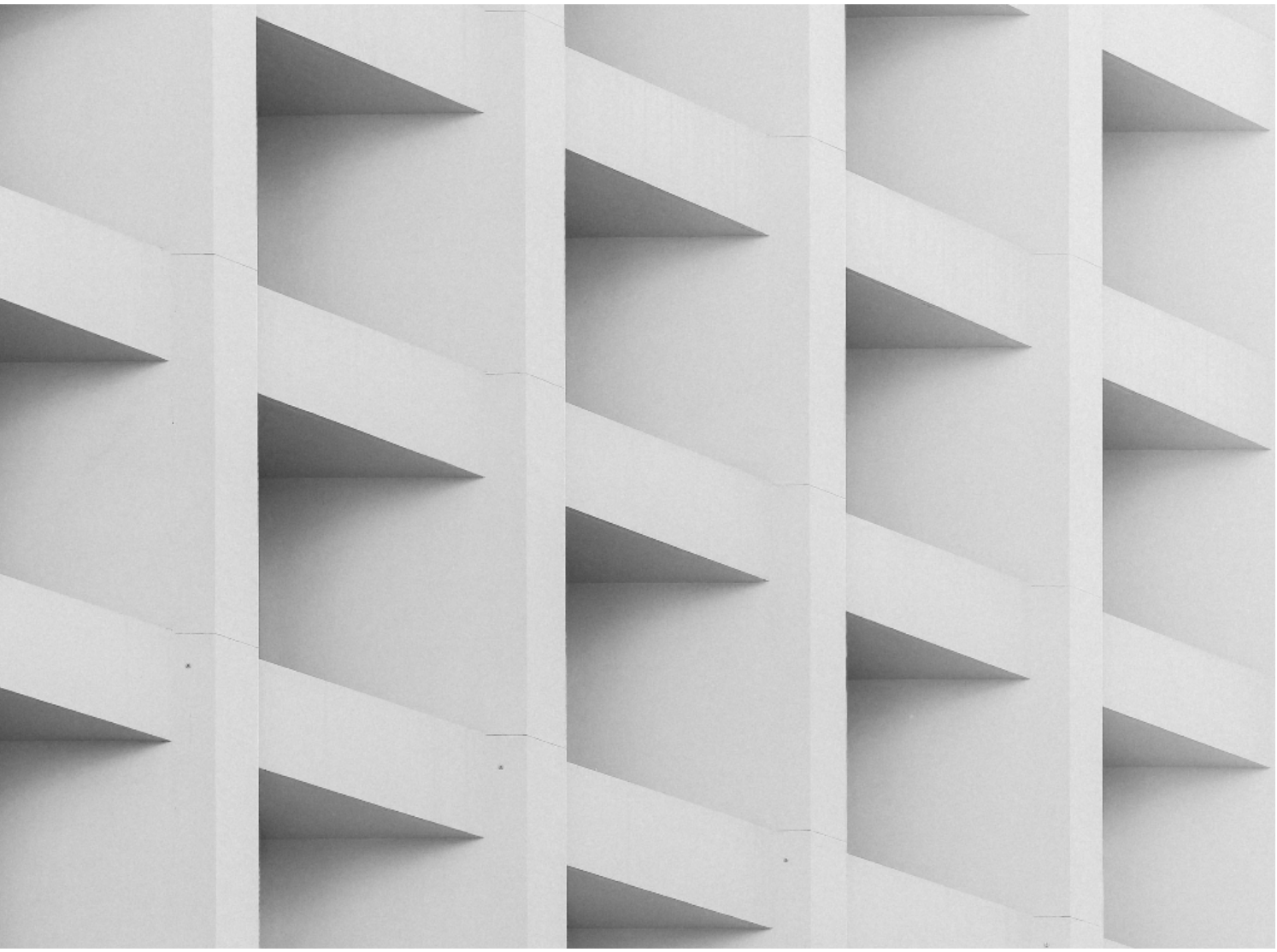
Once published, the stage is set for at least two years of very intensive discussions between the institutions and stakeholders. With high aims, **high stakes, strong competing positions, and a European populace more engaged in health than ever before**, this re-evaluation of many of the basic concepts of pharmaceutical law will have widely felt economic and social consequences.

Methodology & Data Analysis

This report has been prepared by H/Advisors Public Affairs within Havas Group. The insights and analysis has been generated through information gathered by direct engagement and interviews with over 25 European stakeholders during the period December 2022 - February 2023. The stakeholders included MEPs, journalists, health policy advisors from EU-based trade associations, and international patient groups.

The interviews focused on EU healthcare policy in general and specifically on views of the EU pharmaceutical package of legislation currently under revision. In the context of the legislative review, particular focus was placed on the intellectual property incentives framework and how it could address patient access barriers and unmet needs in areas such as rare diseases and medicines for children.

H/Advisors Public Affairs has also reviewed the recently leaked internally circulated version of the pharmaceutical package and has considered it in the context of overall direction of travel and recommendations for engagement in this report.



Stakeholder insights

Health has leapfrogged to top priority status amongst EU policymakers. There is very high awareness that the Commission's review of the general pharmaceuticals legislation marks a once-in-a-generation change.

However, despite recognition of its importance, none of the MEPs consulted for this report feel very familiar with the detail or context of the Commission's review.

The reform proposals will need to tackle unmet need and patient access, whilst considering the interests of future patients, the investors that fund the science, the industry that brings it to patients, and the pressures on national health systems and economies. **The challenge in balancing competing needs highlights how complex the legislative task is.**

The Swedish Presidency has already declared the prioritisation of the legislation and EU stakeholders expect momentum for the Review to build across all political divides during the Spanish Presidency of the Council of the EU and continue during the Belgian Presidency in 2024.

For healthcare to change at an EU level, **it will require country ministers to come together as a co-operative and agree on commonalities.** Historically, this has happened in other sectors such as agriculture, but not health.

The most controversial proposals are expected to surround the intellectual property incentive framework – potentially shorter market exclusivity, tying incentives into market launch timeframes, comparative clinical trials, transferable exclusivity vouchers to promote development of novel antibiotics and how the incentive framework supports the development of medicines for rare diseases and children.

The reform is expected to be a multiple Commission department file. While DG Sante will lead on it, it will also involve working collaboratively with DG Competition, DG Growth, DG Trade and DG CNECT. Beyond the Commission, it will also include multiple committees in the EU Parliament.

Stakeholders predict that the European Parliament could have a plenary vote on one of the pieces of legislation before March next year, but that the election of a new Parliament in 2024 is likely to delay proceedings further.

The fault lines in the review process are already apparent as the macro environment in Europe and unforeseen headwinds continue to evolve rapidly. This will impact what can realistically be achieved within the current legislative cycle ahead of the EU elections next year. **The true ambition of the legislation may may fall short as pricing and access remain national competencies.** To change this would require revisiting the EU Treaties.

Recommendations

1. Considering the significance of the forthcoming review to industry, and its potential impact on business operations across Europe, we recommend widespread and strategic engagement with stakeholders in Brussels alongside targeted Member States. Leadership will need to be familiar with the proposals and advocating on its business impacts.
2. We recommend preparing and presenting data-led insights to key policymakers, showcasing the impact of the proposals on innovation, investment attractiveness and potential impact on R&D spend for future medicines.
3. Given the multiple DGs involved in the commission department file, we recommend that messaging focuses on business resilience and competitiveness for European industry within a global context.

EU Healthcare Policy landscape

The healthcare policy landscape across Europe has changed as a result of the COVID-19 pandemic. Within the European Parliament, this has led to debates focused on healthcare system capacity and workforce, onshoring manufacturing supply chains, and the overall capacity levels of national healthcare systems. MEPs' awareness of health inequalities within the bloc has risen, as access to healthcare continues to vary across the EU. Today, European politicians are increasingly scrutinising where healthcare challenges are arising, and what is driving them, both in a national and an EU-wide context.

An immediate response from the EU to the pandemic was the articulation of the necessity to create a stronger European Health Union. So far, this has resulted in improvements in the EU's preparedness to respond to health crises, such as the creation of the Health Emergency Preparedness and Response Authority (HERA), but MEPs believe little progress has been made on strengthening the day-to-day resilience of healthcare systems at national level.

> ***There are mixed views on what the exact mandate is at EU-level in terms of responsibility for health policy.***

Almost half of those interviewed believe it should be driven by the EU and half believe it should remain at a national government level.

The Pharmaceutical Strategy is recognised as a key cornerstone that supports the vision of a European Health Union and the legislative revisions anticipated by the end of March are recognised as a key and far-reaching step in the process.

Healthcare policy is a core priority for MEPs right across the parliamentary spectrum.

From a public health and disease area, the top concerns of MEPs are as follows:

Cancer

Cardiovascular diseases

Obesity

Mental health

But while MEPs believe the proposals will have a significant impact, none feel very familiar with the detail. This indicates that there will be momentum needed to bridge that gap, articulating the implications for industry and patients, once the Commission officially publishes the proposals.

The research also revealed how quickly the priority area for MEPs can change. During the pandemic, the focus on healthcare as a top priority was almost universal. However, as the economic and social landscape across Europe has progressed, so too have the Parliament's priorities. MEPs are now shifting to address the challenges posed by the sharp rise in inflation and the knock-on impacts it is having on budgets and national economies. This will potentially have an impact on what can be achieved and finalised ahead of the 2024 European elections.

> ***Depending on how these policy discussions develop in the coming years, they will have a direct impact on not just the public affairs function, but the wider business strategy of healthcare businesses operating in Europe.***

From a policy perspective, the following issues are top priorities for MEPs:

Antimicrobial resistance

Research & development

Vaccinations

Over the counter medicine

Health security

Digital health

EU Pharmaceutical Review - anticipated areas of impact

The Commission's proposals for reform are officially expected by the end of March. The result of the Commission's review will change the Internal Market framework for regulating medicines long into the future. Influenced by calls to improve patient access to pharmaceuticals and to address unmet need across Europe, the Commission is expected to revise the intellectual property incentives framework significantly and push through some controversial proposals.

However, a more balanced approach will be advocated for whereby the Commission considers the value of R&D development in Europe for the benefit of patients of the future.

There are four key pieces of legislation likely to be affected by the Commission's review:

General Pharmaceuticals Legislation

Directive 2001/83/EC

General Pharmaceuticals Legislation

Regulation 726/2004

The Orphan Medicinal Products (OMP) Regulation

Regulation 141/2000

The Paediatric Regulation

Regulation 1901/2006

The primary objectives of the Review are to assess the extent to which the first two pieces of legislation listed above (**Directive 2001/83/EC and Regulation 726/2004** - together called the "EU general pharmaceuticals legislation") have delivered on their objectives and identify the key areas where these need to be revised to adapt to the changing global regulatory context, as well as the scientific and technological developments in the pharmaceutical industry.

In addition, the Commission's review also includes an assessment of two separate pieces of legislation on orphan medicinal products (**Regulation 141/2000**) and medicinal products for paediatric use (**Regulation 1901/2006**), to ensure investment is allocated in alignment with key unmet need areas. It is expected that the Review will combine all these pieces of legislation together in the revised approach.

Over half of the MEPs surveyed supported the Commission's plans to reform existing general pharmaceuticals legislation and intellectual property incentives, as one of several ways to address health-related challenges in Europe.

Initial impressions of the leaked draft are that the Review contains some positives, particularly in terms of streamlining processes. However, there appears to be little analysis of how reduced incentives will impact the decision-making process to develop or launch new products in the EU. EFPIA (European Federation of Pharmaceutical Industries and Associations) has been advocating for an agile regulatory framework and a strong incentives system that supports innovation. Whilst acknowledging that the current framework has not covered all the needs of the sector (for example, medicines to treat rare diseases and children), it believes that novel incentives can be adapted to the specific challenges of particular disease areas. Vaccines Europe and the European Confederation of Pharmaceutical Entrepreneurs (EUCOPE) broadly agree with this position.

In contrast, Medicines for Europe is saying that whilst incentives generate some success, they should not go beyond their legally defined objective and delay generic/biosimilar competition. As such, Medicines for Europe has asked for the introduction of incentives and regulatory reforms to encourage the development of follow-on orphan medicines and paediatric products.

efpia

EUCOPE
European Confederation of Pharmaceutical Entrepreneurs AISBL

medicines for europe
better access, better health

Vaccines Europe

The scope of the EU's Incentive Framework

Research & Development

The Commission's proposals will need to balance their ambition to improve access to affordable medicines and address unmet need with supporting the EU's pharmaceutical industry to remain competitive and innovative.

> ***Our research revealed that whilst the overwhelming majority of MEPs described R&D as a high priority for Europe, others said that improving access to medicine was of greatest significance in addressing healthcare challenges at Member State level. This insight is indicative of the tensions expected to emerge in striking the right balance between these two priorities.***

The recently leaked documents highlight that Commission proposals will likely incentivise R&D activity in particular areas where there are high levels of unmet need and in the efforts to produce novel antibiotics.

Conditionality of Intellectual Property Rights

To improve medicine access across the Union, the European Commission is considering legislative measures to compel manufacturers to supply medicines in all EU Member States. This measure is viewed as controversial by the MEPs and industry experts we spoke with.

If the Commission moves to incentivise broader launches, pharmaceutical companies will be forced to think about a wider range of markets from the outset. This will have commercial implications given variabilities within Member States for funding of new medicines. Furthermore, launching products in different economies within a set time period could trigger the unwanted consequence of market shortages due to potential movement of imported medicines between markets.

Some MEPs, particularly those in larger and wealthier Member States, have publicly supported EFPIA's recent member commitment: ***"To file for pricing and reimbursement in all EU countries no later than two years after central EU market authorization"***.

This position has been supported by the publication of additional data which highlights complex processes and delays which hinder national approval of pricing and reimbursement for new medications. Other MEPs believe that the commitment of EFPIA member companies does not go far enough to support the availability of innovation medicines across EU Member States. They believe this is a challenge which can and should be solved at EU level.

The Commission is currently focused on amending Regulatory Data Protection (RDP). RDP is an intellectual property right which provides a period of protection for clinical trial and other test data pharmaceutical companies use to prove a medicine is safe and effective. By making two years of a previously eight-year incentive conditional on product launch in all 27 Member States, the Commission could in some instances enable biosimilar and generic products to enter the market sooner.

Unmet Need

The Orphan Medical Products (OMP) Regulation and the Paediatric Regulation were designed to incentivize the development of medicines for the treatment of uncommon conditions.

Despite improvements in the landscape, there are still over 7,000 rare diseases of which 95% have no treatment option and many of which affect children. A Commission-ordered evaluation of the regulations was published in August 2020 and was followed months later by the EU Pharmaceutical Strategy which made the review of both regulations a policy priority. The Commission's prioritization of this policy area has reached the attention of MEPs, with two-thirds of those sharing a belief that rare diseases are an area of focus for Ursula Von der Leyen's Commission.

The OMP Regulation and Paediatric Regulation are being revised together and proposals will go further in incentivizing the development of medicines in areas of unmet need. The final proposals will likely include a variable duration of market exclusivity based on the type of orphan medicine and whether it address high unmet medical need. Meanwhile, the Commission is looking at streamlining processes and regulation around Paediatric Investigation Plans (PIP) so it's more straightforward for providers to access the incentive.

AMR

The COVID-19 pandemic fueled the ongoing antimicrobial resistance (AMR) global crisis due to the increase in the use of antibiotics to treat COVID-19 patients, disruptions to infection prevention and control practices in overwhelmed health systems, and diversion of human and financial resources away from monitoring and responding to AMR threats.

Moreover, the pandemic shone a light on global health security and ignited a growing awareness of the need to continue prioritizing an AMR response including the urgent development of breakthrough medicines to fight infections. The MEPs we spoke with cited it as the top healthcare concern across Europe and recognised new incentives were needed to boost progress in this field.

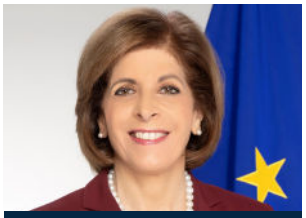
> ***The Review is expected to propose a 'transferable exclusivity voucher' (TEE) to fund products that fight drug-resistant microbes, by allowing developers to use or sell the right to extend the exclusivity of another product. However, the proposal is divisive.***

The conditions for grant and use are considered strict and possibly not as "incentivising" as they might be. Meanwhile concerns have been raised by patient groups that TEE could lead to increased costs from lost genericisation of other medicines.

Examples of key players and recent positions

The Commission

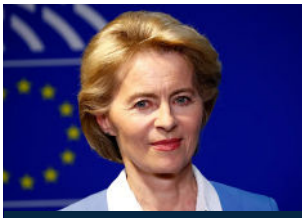
The European Commission is the EU's executive arm responsible for drafting legislative proposals. The Commissioner for Health is elected by the European Parliament and heads the Directorate-General for Health and Food Safety (SANTE).



Stella Kyriakides
Health Commissioner

"Our objective is to secure access to medicines for all patients in need and to avoid any market disruption of medicines in the EU."

Tackling antimicrobial resistance as well as access inequality is one of her stated goals.



Ursula von der Leyen
President of the European Commissioner

"The coronavirus pandemic has highlighted the vital need to strengthen our health systems, including improving access to safe, effective, and high-quality medicines at an affordable price. Intellectual property must be protected, however, as in a global emergency like the pandemic, if voluntary licensing fails, compulsory licensing is the legitimate tool to scale up production."

Margaritis Schinas
Vice-President of the European Commissioner

"Effective and safe medicines, vaccines and treatments have helped to tackle some of the leading causes of disease and life-threatening illnesses in the past. This strategy supports the EU's pharmaceutical industry to remain competitive and innovative, whilst addressing the needs of the patients and our health systems."

Sandra Gallina
Director General for Health and Safety

"There are fascinating projects that will continue to need my steer: Pharma Strategy, European Health Union, Cancer Plan, European Health Data Space, AMR, Farm to Fork and food sustainability framework legislation, Food Waste, Sustainable Use of Pesticides, Animal Welfare, Food labelling, New Genomic Techniques, just to mention a few."

Sylvain Giraud
Head of Unit – Medical Products, Directorate-General for Health and Food Safety (DG SANTE).

"We need resources, capacity building and leadership, to take into account specificity and recognise fragmentation of the market."

"Cost-effectiveness remains an important policy objective... but it's not necessarily a tradeoff".

Members of the European Parliament

One of the most important stakeholders involved with the legislation will be the MEPs appointed as rapporteur and shadow rapporteurs. The below individuals spearheaded a non-legislative parliamentary report on "A Pharmaceutical Strategy for Europe" in 2020, outlining the institution's views and expectations. They may be expected to play a role once the European Parliament picks up legislative work on the Pharmaceutical Review.

Dolors Montserrat

Rapporteur in Committee with responsability.

European People's Party (Christian Democrats), Spain.

Committee on the Environment, Public Health and Food Safety (ENVI).

"Twenty years have passed since the last strategy and the world has changed; For this reason, we must update the laws and the incentive system: the new strategy is the ideal framework for updating and reinforcing a new generation of pharmaceutical regulations for this decade.

This [new] strategy strikes a balance between promoting innovation, patient access and the sustainability of our national healthcare systems in Europe, putting patients at the center of all policies. The health of Europeans depends more than ever on the health of the European Union and I am very convinced that the European Health Union is one of the great pillars of this European Union."

Marc Botenga

Rapporteur for opinion.

The Left GUE/NGL, Belgium.

Associated Committee on Industry, Research and Energy (ITRE).

"We feel that there is something rotten in the pharmaceutical sector. Many innovations presented to us by pharma companies offer little to no improvement for the patient. Multinational companies artificially extend the duration of their patents to make us pay more for drugs. The proposed strategy is to collaborate more with Big Pharma and let them influence our policies in a structural way.

You even want to put pressure on states that would like to force Big Pharma to share drugs. I think we must change course and the strategy should prioritize reducing our dependency on big pharmaceutical multinationals. As the Parliamentary Committee on Industry notes, it is time to create a public biomedical infrastructure in the European Union."

The European Parliament

There are 705 MEPs in the European Parliament, and it can be assumed all have a modest interest in healthcare and therefore, considering its national importance, the Review. Whilst there will be hundreds of MEPs involved with the legislation at the surface-level, there will be between 15 and 30 that will be into the detail and truly working hard to swing the outcome.

The MEP-sponsored letters from autumn last year reveal that there are conflicting attitudes within the Parliament as to what the pharmaceutical package should address. A letter published in October signed by 35 MEPs from the center-right wing of the Parliament called for the Commission to ensure that the revised legislation "creates more jobs, strengthens the EU's export position and global competitiveness, and stimulates the pharmaceutical industry to develop the medicines that we need". In particular, the letter highlighted three key priorities: attracting more research and clinical trials to take place in the EU, strengthening incentives for treatments for rare diseases, and tackling the inequalities across the EU in access to medicines.

The Pharma Strategy's rapporteur for opinion, Marc Botenga MEP, however, responded to the letter stating that he found a "fundamental flaw in the reasoning [these MEPs] have, which basically implies that more profits for pharmaceutical companies means more investment in research and development." Botenga stated that this rhetoric is used by pharmaceutical companies "to justify their enormous profits, but there is no empirical proof that this money is invested and not going to shareholders."

Whilst these MEPs will likely play a role over the next year, it must be caveated that this list may change post EU 2024 elections.

Tomislav Sokol

European People's Party (Christian Democrats), Croatia

"As an MEP who has been insisting on the creation of a European Health Union, I strongly advocate the extension of joint procurement to medicines for cancer and rare diseases. This will strengthen the negotiating position of smaller and less developed member states, achieving a reduction in prices. In this context, the establishment of a European Fund for the Procurement of Medicines for Rare Diseases would be of great importance so that patients of all member states have equal access to these, often very expensive, medicines."

Susana Solis Perez

Renew Europe, Spain

"With this pharmaceutical strategy, we are taking another step to protect the companies who worked hard to recover the competitiveness of a strategic industry in which Europe was once the leader. Today, we are very far from being autonomous in the pharmaceutical field. To resume this leadership, we need to provide the industry with sufficient legal certainty to encourage it to invest the time and enormous resources necessary to develop new medicines."

Cesar Luena

Progressive Alliance of Socialists & Democrats, Spain

"Some measures to support the pharmaceutical industry ignore a social component. A new system of research incentives is proposed, but the report does not mention the misuse that has been made of some of these incentives; in the framework of the Regulation on orphan drugs, the report talks about transparency and price fixing, and we should have a harmonized criteria for this. It talks about introducing centralized purchases in exceptional cases, but they should be the general norm. I also want some mention of plasma, because we are entirely dependent on third countries."

Veronique Trillet-Lenoir

Renew Europe, France

"Guaranteeing patient health whilst remaining health system sustainability must be a priority. The strategy's implementation must include four legislative measures. First, to guarantee access to affordable and safe medicines by revising and updating legislation on access to medicines. Second, to restore pharmaceutical independence through a partial repatriation of drug production to Europe. Third, boosting and accelerating R&D of innovative drugs. Finally, addressing the issue of drug prices."

Alessandra Moretti

Progressive Alliance of Socialists & Democrats, Italy

"Now is the time to create a true European Health Union, in which all citizens finally see their right to a quality public health system recognized and guaranteed, with minimum standards of health care valid throughout Europe. We need maximum transparency and traceability of public funds, with the determination of drug prices which cannot be determined by how important this drug is for patients, but which must be linked to the real costs of research and development."

Pernille Weiss

European People's Party (Christian Democrats), Denmark

"[The review] is the easy part of the political craft. The hard part is pointing out how companies can deliver. The main task is to ensure that industry and the thousands of SMEs continue to choose the EU as their home, for the sake of the patients, and the economy. This industry throws money into the public coffers every year that we need for everything we promise our citizens to be possible."

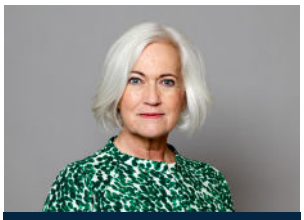
EU Member States

EU Member States are represented in the Council of Ministers to discuss, amend and adopt laws, and coordinate policies. Depending on the severity of the issue and of an industry's relations to particular countries, country-level engagement will be required to assure a favourable outcome in Council.

Vlastimil Válek

Czech Deputy PM and Minister of Health

On the pharma review: "It is difficult to say because we expect the Commission's proposal, and only after that we can start the discussion. Unfortunately, I don't know if we will have enough time to continue the conversation during our presidency."



Acko Ankarberg Johansson

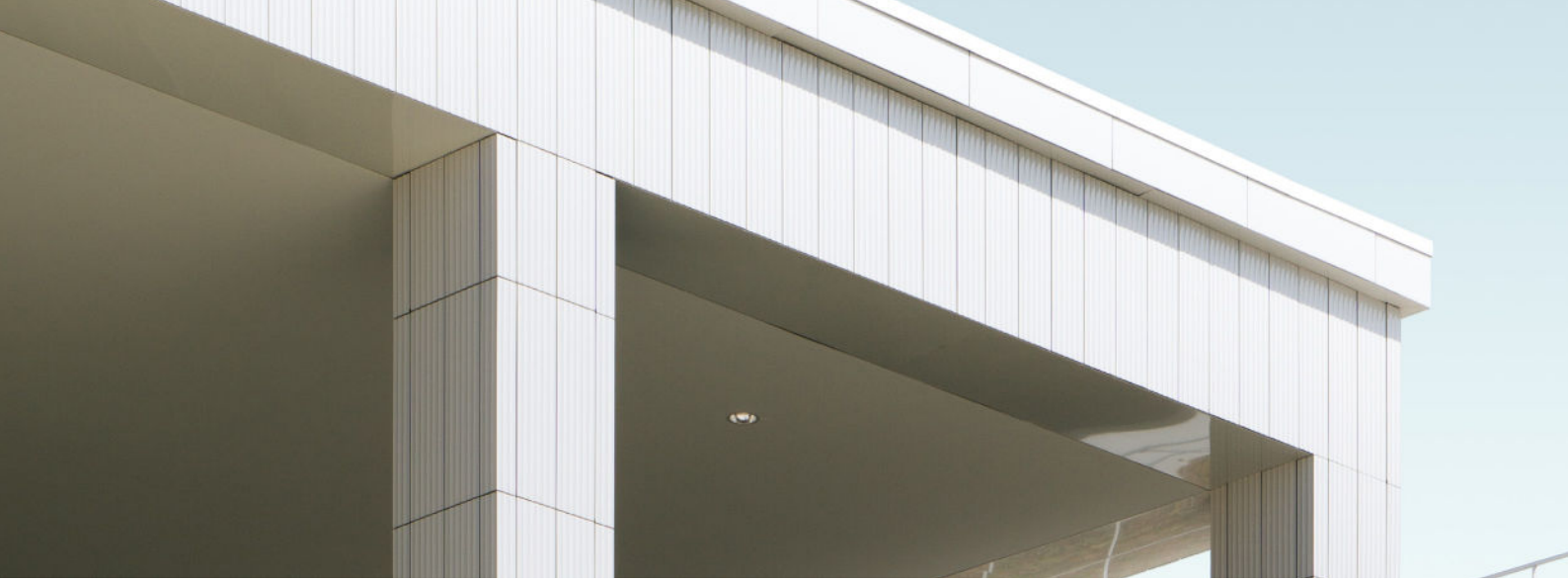
Swedish Health Minister

"We have problems with the supply chain and we have lacks because there are certain medicines that have not been developed, and which may be needed in different areas."

Carolina Darias

Spanish Health Minister

"Europe must make further progress on coordinated responses to health challenges". Darias stressed the importance of Europe continuing to make progress in coordinated responses to health challenges, including solidarity vaccination and aid to the people of Ukraine."



The EU Pharmaceutical Review - what's next?

Sweden, which took over the rotating presidency of the Council of the EU in January 2023, has said it will prioritise a number of health-related initiatives in the first half of the year, including the revision of the EU pharmaceutical legislation and the revisions to the regulations on orphan and paediatric medicines. The question remains how much can be achieved as the clock ticks towards next year's election cycle.

On average, a legislative file is completed in 18 months, which provides industry with the necessary time to engage and influence the outcome. In this case, the development of proposals which revise existing pharmaceutical regulation has taken longer than anticipated. Although originally planned for publication in December 2022, a lack of agreement between stakeholders led to a delay and the proposals are now expected by end of March 2023. Once published, the Commission will open a public consultation for a duration of 8 weeks, which allows interested stakeholders to express their views on the proposals. The Commission will then share a summary of this feedback with the European Parliament and the Council.

The text of proposals will be scrutinised over separately by relevant European Parliament Committees and the Council's working groups. The two institutions will work in parallel to develop their own recommendations on the proposals and will each work out their sets of amendments.

This is a critical period for stakeholders to engage with both institutions and share their views.

> ***Even with renewed momentum, given the delays so far, there is now the chance that the Commission's proposals will not complete their legislative journey before the 2024 European Parliament elections***

Sector experts believe that there might be time for a single plenary vote before Parliament's legislative agenda is suspended for the election. Such progress would enable a new Parliament to pick up files where the previous Parliament left them. However, if Parliament does not vote before the election, there risks being no legally valid Parliamentary position, with work done during the previous parliamentary term lapsing.

Nonetheless, whether the Commission's proposals are passed in their current format or not, the significance of the issues that they have highlighted will not diminish, and it remains in the interests of industry to continue proactive engagement with this process.

Timeline

A Pharmaceutical Strategy for Europe' published November 2020.

2021

Consultation Process: Feedback period 30 March 2021 – 27 April 2021.

Public consultation 28 September 2021 – 21 December 2021.

Debate in Parliament about report on the Pharmaceutical Strategy Nov 2021.

2022

Commission adoption: Originally planned for publication in December 2022

2023

We are here

Anticipated publication of Review - end of March 2023

Post-release of Commission proposals: 8-week period for stakeholders to feedback on the proposals and impact statement.

Council accepts/declines the Parliament's decision.

European Parliament adopts a position.

Specialist lawyers reviewing the proposals and translators translating them into 24 different languages.

2024

EU Parliament elections 2024: Election proceedings may delay the passage of the pharma legislation and many doubt whether the proposals will enter into law before 2025.

About H/Advisors

H/Advisors is a global organization of strategic communications advisors dedicated to building, enhancing, and protecting clients' reputations and helping them achieve their business and public affairs objectives. H/Advisors is part of Havas Group, one of the world's largest global communications networks.

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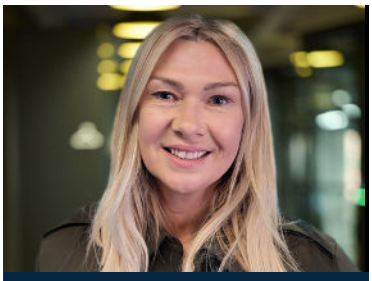

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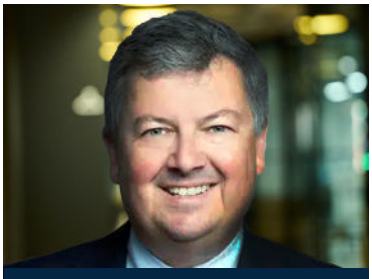

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