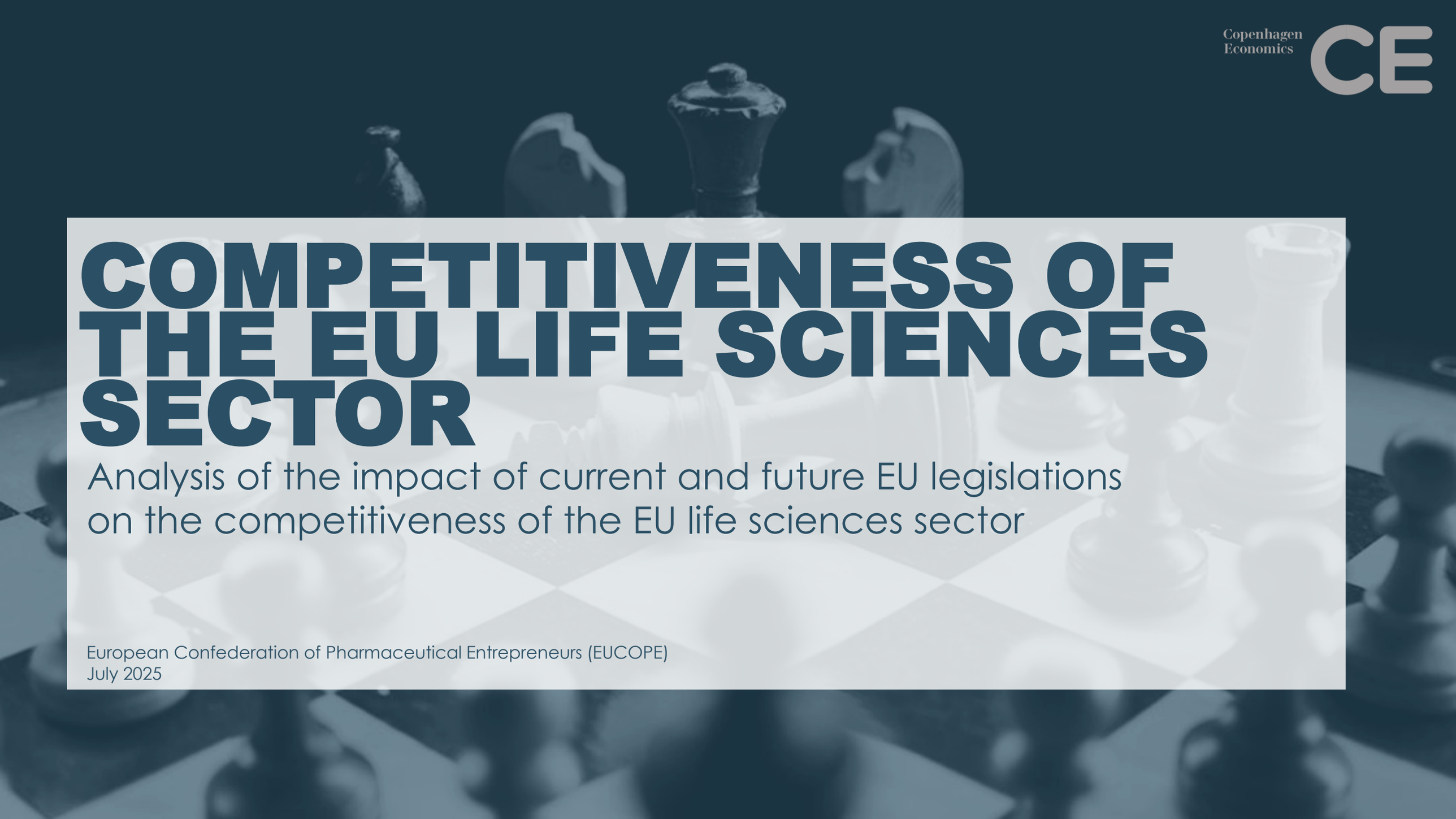

COMPETITIVENESS OF THE EU LIFE SCIENCES SECTOR

Analysis of the impact of current and future EU legislations on the competitiveness of the EU life sciences sector

Copenhagen Economics

European Confederation of Pharmaceutical Entrepreneurs (EUCOPE)
July 2025

Executive summary (1/2)

In 2024, Mario Draghi's report on *The Future of European Competitiveness* warned that the EU is lagging in pharmaceutical innovation due to a fragmented and complex regulatory system that hampers investment and delays access to new treatments. In response, the European Commission introduced the Competitiveness Compass in January 2025 - a strategic plan focused on simplifying regulations, reducing bureaucracy, and boosting innovation through new legislative initiatives.

Against this background, we assessed the expected impacts of 10 key legislations on the competitiveness of the EU life sciences sector, see page 4. Drawing on existing literature and interviews with EUCOPE member companies, we assessed the likely direction of impact of each legislative initiative focusing on impacts on capacity to innovate, cost of compliance, international competitiveness, and market access. We rate the impact of each initiative as positive (green), negative (red), or unclear/ambiguous (yellow).

We find that across legislations, the EU has some way to go to fulfil the ambitions of the Draghi report.

Across the legislations, the EU has not (yet) sufficiently seized the opportunity to improve capacity to innovate

We assessed the legislations' impacts on **capacity to innovate**, i.e. on the sector's ability to translate scientific research into market-ready innovations. We find that while several legislations, such as the **Clinical Trials Regulation (CTR), the EU Health Technology Assessment (HTA) Regulation**, and the proposed **General Pharmaceutical Legislation (GPL),** intend to improve capacity to innovate by **streamlining processes and incentivising research and development**, their impacts are likely to be mixed. The proposal for the revision of the GPL, for instance, proposes measures to enhance regulatory efficiency but counterbalances these with a reduction in baseline regulatory data protection, undermining the investment case for new medicines with uncertain impacts on **incentive extensions for investment decisions.** Meanwhile, harmonisation efforts under the CTR and HTA Regulation risk consolidating, rather than reducing, national differences, leaving persistent implementation gaps and complex procedures that slow innovation. In turn, the **European Health Data Space (EHDS) Regulation** holds considerable potential to strengthen the capacity for health technology innovation through the accessibility of large data sets, but its impact crucially depends on harmonised implementation across Member States. Looking ahead, the proposed **Biotech Act** offers significant promise for strengthening the sector's capacity to innovate.

A further group of regulations primarily pursue safety-related objectives. While such regulations are not expected to directly boost innovation capacity, they currently have a stifling impact on capacity to innovate. The **Medical Device Regulation (MDR) and In Vitro Diagnostics Regulation (IVDR)** have led to slower and more unpredictable regulatory pathways compared to previous frameworks, and the **GMO framework,** originally designed for agricultural products, imposes parallel and partially overlapping registration requirements on advanced therapy medicinal products (ATMPs), delaying clinical development. Similarly, the **Artificial Intelligence (AI) Act**, though designed to ensure safe and trustworthy AI use, may inadvertently constrain innovation in medical devices due to misalignments with the MDR and IVDR, despite offering exemptions to promote pharmaceutical R&D. While **sustainability legislations** are essential for the protection of the environment and human health, the current regulatory set-up of EU sustainability legislations imposes a cumulative burden, contradictory demands and uncertainty that risks weakening the competitiveness and innovative capacity of the EU pharmaceutical industry.

Cost of compliance is rising

We find that, as new and amended regulations expand monitoring and documentation requirements, **compliance costs** have increased. Initiatives such as the CTR, Medical Device Regulation (MDR), In Vitro Diagnostics Regulation (IVDR), AI Act, and GMO Directives have led companies – especially small and mid-sized companies - to allocate more to regulatory tasks rather than innovation. Even harmonisation-focused regulations such as the CTR and EU HTA Regulation have not reduced compliance burdens, due to risks of duplication between EU and national processes. Inconsistencies and overlaps among legislative instruments, along with the involvement of multiple regulatory bodies, continue to create a fragmented environment that can affect the predictability for companies seeking to bring innovations to market.

Since the foreseen Biotech Act includes provisions aimed at regulatory simplification, it remains to be seen whether the Act can markedly improve upon the current situation and reduce compliance costs.

As a result, the EU may not close the widening international competitiveness gap

International competitiveness refers to the ability of EU-based companies to compete successfully in global markets in terms of innovation, investment, and market share, but also to the international competitiveness of the EU regulatory framework itself. We find that the current legislative landscape, taken as a whole, is not sufficient to close the widening international competitiveness gap.

Executive summary (2/2)

The GPL, EU HTA Regulation and CTR aim to make the EU a more attractive place to launch by streamlining regulatory processes, enhancing scientific support, and harmonising previously fragmented systems. However, the potential negative effects of a baseline reduction of RDP/MP, a complex modulation system, and continued duplication and burdensome procedures risk limiting these benefits of the regulations.

By contrast, regulations such as the **MDR/IVDR, the GMO Directives, and the AI Act** impose stricter rules and more onerous documentation requirements than those seen in other jurisdictions, such as the US. In the case of ATMPs, the EU requirement for a GMO risk assessment prior to clinical trials makes the EU a less attractive destination for development compared to the US. Moreover, the **stringent and multiple environmental legislations** in the EU add to the overall system complexity and are costly to observe, thereby risking to dissuading development of medicinal products in the EU.

The two legislations expected to boost international competitiveness are the **EHDS Regulation and the Biotech Act**. The EHDS could put companies conducting R&D in the EU at a competitive advantage by enabling access to large amounts of electronic health data, while the Biotech Act - if sufficiently ambitious - can strengthen the EU R&D ecosystem and translational outcomes; however, **both depend on effective implementation to realise their full impact**.

Given current legislations, speed of market access will likely not improve

We further assessed how the legislations affect the speed at which companies' innovations can reach the market, the complexity of market access processes, or the expected revenues at launch. We find that a **first group** of legislations - comprising the EU HTA Regulation, the EU GPL, and the Critical Medicines Act (CMA) – explicitly aims to improve and accelerate market access procedures across the EU. However, the provisions currently envisaged under these regulations raise doubts about their ability to deliver on this ambition.

A **second group** of legislations - including the MDR/IVDR, the AI Act, and the GMO Directives – is primarily focused on safety, and individually or collectively appears to extend the time to market for medical devices and ATMPs. The combined effect of longer approval timelines, additional documentation requirements, and fragmented implementation across Member States risks delaying access for EU patients and may lead companies to prioritise non-EU markets.

A **third group** of legislations – comprising the CTR and EHDS Regulations, and the Biotech Act – could positively impact time to market, depending on how they are implemented. While these initiatives aim to accelerate clinical trial activity, enhance use of real-world data, and streamline regulatory pathways, their success will depend on overcoming national-level barriers, effective data harmonisation, and the definition of concrete implementation mechanisms.

Ultimately, the EU life sciences sector competitiveness also hinges on market access conditions themselves

The ability of the EU life sciences sector to commercialise innovations efficiently and generate revenue is closely linked to market access conditions. In 2024, nearly half of innovative medicines were still unavailable to patients, and the average waiting time for orphan medicines has increased. Navigating market access across 27 Member States can be complex and costly, particularly for smaller companies. To strengthen competitiveness, EU countries must urgently work towards an access landscape that enables pharmaceutical companies to reach a broad share of the market as swiftly and efficiently as possible. Ensuring that prices reflect the therapeutic value of treatments - and that they adequately reward the investment and risks involved in their development - is essential to sustain innovation.

Overview of legislative impacts on competitiveness and market access

Overview of legislative impacts on competitiveness and market access

Piece of legislation		Overall competitiveness assessment	Competitiveness assessment			Market access
			Capacity to innovate	Cost of compliance	International competitiveness	
EU Health Technology Assessment						
Clinical Trials Regulation						
Medical Device Regulation & In Vitro Device Regulation						
Artificial Intelligence Act						
Deliberate release of GMO & Contained use of GMM						
European Health Data Space						
EU General Pharmaceutical Legislation						
Critical Medicines Act			Critical medicines			
			Medicines of common interest			
Patent Package	Unitary SPC					
	Compulsory Licensing (CL)					
Biotech Act						

Negative impact | Unclear/ambiguous impact | Positive impact | Not relevant

DISCUSSION

We assess the likely impact of key EU legislations on the competitiveness of the life sciences industry

The EU must urgently reform its regulatory landscape to boost the global competitiveness of its life sciences sector

In 2024, Mario Draghi's report *The Future of European Competitiveness* sounded a clear warning: The EU is falling behind in key areas of pharmaceutical innovation, namely biologicals, orphan medicines, and advanced therapy medicinal products (ATMPs).[1] One of the primary causes identified is the EU's slow, fragmented, and overly complex regulatory environment, which increasingly deters investment and delays patient access to innovation.

Responding to this call for action, the European Commission launched the Competitiveness Compass in January 2025 – a strategic roadmap designed to restore the EU's economic dynamism.[2] Among its priorities are simplifying rules, reducing administrative burden, and unlocking the full potential of the single market for businesses. Flagship initiatives such as the Critical Medicines Act and the Biotech Act are core components of this effort, aimed at removing barriers and accelerating innovation across the continent.

Building on this momentum, we assess the likely impact of key EU legislations on the competitiveness of the life sciences industry

We have analysed the impact of ten current and forthcoming EU-level legislative initiatives on the competitiveness of the life sciences industry in the EU, see Table 1. In addition to these ten pieces of legislation, we also consider broader policy developments in the area of sustainability.

The aim of our analyses is to assess whether current and future legislation is steering the EU in the right direction for maintaining a competitive life sciences sector. To this end, we apply the principles outlined in the European Commission's competitiveness check, focusing on the impact of legislation on innovation capacity, compliance costs, international competitiveness, and market access.

Our analysis is qualitative in nature. Drawing on existing literature and interviews with EUCOPE member companies, we assess the likely direction of impact of each legislative initiative: compared to the current state, and holding all else equal, does a given piece of legislation enhance, weaken or maintain the sector's competitiveness? We rate the impact of each initiative as positive (green), negative (red), or unclear/ambiguous (yellow). The results are summarised in a briefing per piece of legislation in appendix.

Two important considerations should be borne in mind when reviewing our findings. First, most of the legislation examined has either only recently entered into force or remains at the proposal stage. As such, we are assessing expected rather than observed impacts and do not draw on market data relating to actual outcomes. Second, not all the legislations in question are intended to enhance the competitiveness of the sector. Some have primary objectives related to safety, such as environmental protection, supply security, or the ethical use of emerging technologies. These types of regulation often have a negative effect on businesses' competitiveness, as they impose constraints and increase compliance requirements. Evaluating whether such impacts are proportionate to the importance of the primary objective is a separate exercise, which we do not undertake here. Instead, we focus solely on the impact on competitiveness.

Table 1. Legislations included in this analysis

Applied legislations	**1**	EU Health Technology Assessment Regulation (HTAR)
	2	Clinical Trials Regulation (CTR)
	3	Medical Device Regulation & In Vitro Diagnostics Regulation (MDR & IVDR)
	4	Artificial Intelligence Act (AI Act)
	5	GMO Framework
	6	European Health Data Space (EHDS) Regulation
Proposed legislations	**7**	EU General Pharmaceutical Legislation (GPL)
	8	Critical Medicines Act (CMA)
	9	Patent Package
Anticipated legislations	**10**	Biotech Act
Broader policy developments	**11**	Sustainability legislations

1) European Commission (2024), The future of European competitiveness. Part B, see link. / 2) European Commission (2025), Competitiveness compass, see link.

Complexity and weakening of incentive frameworks affect capacity to innovate

The Draghi Report underscored the strategic importance of the life sciences sector as a cornerstone of the EU's competitiveness, innovation capacity, and economic resilience. As one of the continent's most R&D-intensive industries, the sector does not only contribute significantly to high-value employment and trade surpluses but also drive broader innovation ecosystems, including biotechnology, advanced manufacturing, and digital health. Ensuring a competitive pharmaceutical industry is therefore not only about fostering growth, but also about reinforcing the EU's sovereignty in critical technologies and securing long-term prosperity.

The report identified two major opportunities for the sector: enhancing its translational capabilities through US-style innovation clusters and harnessing the transformative potential of artificial intelligence (AI). At the same time, it highlighted key challenges – most notably, that innovation, particularly among smaller pharmaceutical companies, is hindered and delayed by complex and fragmented regulatory frameworks.

The EU still has some way to go to fulfil the ambitions of the Draghi report

Our review of ten legislations, see overview on page 4 and 6, and broader policy developments in the area of sustainability confirms that regulatory complexity and fragmentation will remain significant barriers to European competitiveness and market access. Even regulations that explicitly aim to reduce fragmentation and enhance harmonisation often suffer from an implementation gap, as Member States fail to align sufficiently or, in some cases, duplicate regulatory efforts in relation to EU-level frameworks. Meanwhile, the EU General Pharmaceutical Legislation – despite its stated objective of improving the environment for pharmaceutical innovation – currently lacks proposals likely to deliver a step-change in competitiveness. The forthcoming Biotech Act now holds the potential to address this missed opportunity.

Across the legislations, the EU has not (yet) sufficiently seized the opportunity to improve capacity to innovate

Capacity to innovate refers to the sector's ability to translate scientific research into market-ready innovations. Legislation that strengthens R&D incentives (such as intellectual property protection) or improves access to key resources (such as skilled labour, financing, and infrastructure) enhances this capacity. Additionally, greater efficiency in regulatory approvals supports innovation by allowing companies to reallocate resources from administrative processes to R&D while also accelerating the time it takes for new products to reach the market. We find that, across the studied legislations, the EU has not yet sufficiently seized the opportunity to improve the sector's capacity to innovate.

Several of the legislative initiatives under review explicitly aim to boost the sector's capacity to innovate. However, their actual impact is likely to be mixed.

The European Commission proposal for the revision of the **EU General Pharmaceutical Legislation (GPL)** includes many different measures intended to increase regulatory efficiency and thereby enhance innovation capacity – for example, by reducing regulatory timelines (although undermined by the recent position by the Council), establishing regulatory sandboxes, and offering scientific support to medicine developers. These are expected to markedly increase companies' capacity to bring innovations to the market swiftly. Yet, these positive measures of the GPL risk being offset by the Commission proposal of reducing baseline incentives, specifically the shortening of the baseline regulatory data protection (RDP) and/or market protection (MP) period. Effective lower protection dampens investment incentives and leads to a reduction in R&D investments: empirical research has shown that a one-year reduction in the mean effective protection period is associated with 11.89% lower pharmaceutical R&D investments in the long run.[1] A further study has quantified the long-term annual R&D loss of a one-year reduction of RDP in the EU at EUR 1.64bn.[2] The proposed modulated incentive framework allows companies to earn extensions to RDP if certain conditions are met. However, the lack of predictability around fulfilling these conditions significantly limits the effectiveness of such extensions and reduces investments as investors base their valuations on baseline protections.[3] As a result, they do not meaningfully improve the attractiveness of investment and do not drive innovation incentives beyond current levels.

In any case, even a net addition in the number of years in protection may likely not be sufficient to trigger a step-change in innovation in areas of high unmet need.[4] We note that, apart from a transferable exclusivity voucher for AMR, the legislation has not introduced any novel incentives for developing high-risk, high-cost and high-value medicines.

The **Clinical Trials Regulation (CTR)** and the **EU Health Technology Assessment (HTA) Regulation** both aim to harmonise and streamline two crucial aspects of medicine development and commercialisation: clinical trial approval and clinical assessment. These regulations were introduced in response to the fragmented landscape across 27 Member States and, through harmonising and streamlining those 27 frameworks into one, they could enhance the sector's capacity to innovate. The CTR, for instance, promises to simplify and ease the burden of conducting clinical trials in the EU, while also introducing transparency that can foster scientific collaboration and knowledge-sharing. Through this, the CTR aims to attract more clinical trials to the EU. In 2023, the EEA accounted for 9% of clinical trials globally – a decline from 18% in 2013 reflecting that the EEA captured a lower share of overall increasing global clinical trial numbers.[5]

1) Copenhagen Economics (2018), Study on the economic impact of supplementary protection certificates, pharmaceutical incentives and rewards in Europe, p. 101, see link. / 2) Copenhagen Economics (2024), Cost and value of regulatory data protection, see link / 3) FTI Consulting for EUCOPE (2024), The Economic Lens: Understanding what makes the EU attractive for life science investments, see link. / 4) Copenhagen Economics (2023), Innovating for people living with a rare disease, p. 29, see link. / 5) EFPIA (2024), Assessing the clinical trial ecosystem in Europe p. 13, see link.

Failure to effectively reduce fragmentation further compound negative effects on innovation capacity

Similarly, the EU HTA Regulation has the potential to reduce duplication of effort for market access, align development with evidence needs, and accelerate time to market.

However, both regulations risk falling short of their potential. Rather than fully streamlining procedures, they may in fact consolidate the diverse requirements of 27 Member States into a single, more complex and burdensome process. Under the EU Joint Clinical Assessment (JCA), for example, developers may be required to respond to multiple PICOs – similar to the previous system – but now within a compressed 90-day timeline. In addition, the limited availability of joint scientific consultations restricts opportunities to align clinical development with HTA expectations. Finally, the non-binding nature of the JCA for Member States may perpetuate the current fragmentation of clinical assessments across the EU.

Similarly, despite the CTR's aim to simplify clinical trial authorisations via a single EU portal, companies report ongoing delays and complexities. For example, the ability of Member States to impose additional requirements has thus far undermined the regulation's harmonisation objectives.

As both the CTR and EU HTA Regulations have only recently entered into force, their full impacts cannot yet be conclusively assessed. Nonetheless, the emerging implementation challenges already warrant a response from policymakers, who should act to pursue further streamlining.

In a similar vein, the **European Health Data Space (EHDS) Regulation** holds considerable potential to strengthen the capacity for health technology innovation. Access to large, harmonised datasets across the EU could facilitate broader and faster research and development of new therapies, as also noted by health commissioner Kyriakides in June 2022.[1] However, the positive impact of this regulation will depend heavily on harmonised implementation. Without strong coordination, Member States may diverge in their interpretations of data access rights, technical standards, and opt-out mechanisms. Such divergence could compromise interoperability and undermine the anticipated gains in scale.

The **Patent Package** seeks to simplify and harmonise intellectual property procedures across the EU, thereby enhancing predictability and improving the overall investment environment. This includes reform of the Supplementary Protection Certificate (SPC) system, with simplified rules and centralised procedures designed to support greater innovation capacity. To ensure that the new EU-wide compulsory licensing mechanism becomes a reliable and predictable instrument, its scope must be clearly defined and limited to genuine crisis situations.

Looking ahead, the proposed **Biotech Act** offers significant promise for strengthening the sector's capacity to innovate. Its ambitions extend beyond harmonising single market rules and aim to address structural barriers within the EU R&D ecosystem - particularly access to funding and the development of biotechnology clusters. Whether the Act delivers on this potential will depend on how it is developed and implemented in the coming months.

A second group of regulations primarily pursue safety-related objectives. While such regulations are not expected to directly boost innovation capacity, they currently have a stifling impact on capacity to innovate.

The **Medical Device Regulation (MDR) and In Vitro Diagnostics Regulation (IVDR)** were introduced to strengthen the safety, quality, and transparency of medical devices and diagnostics across the EU through more rigorous regulatory oversight and harmonised standards. However, the regulations have led to slower and more unpredictable regulatory pathways compared to previous frameworks. Increased documentation requirements have delayed certification processes by up to 12 months, while the lack of alignment among notified bodies has created further uncertainty, thereby discouraging innovation.[2]

The **GMO framework,** originally designed for agricultural products, imposes parallel and partially overlapping registration requirements on advanced therapies such as ATMPs, delaying clinical development. The exemption for ATMPs from the GMO framework proposed in the revised GPL is therefore a welcome and necessary step forward.

In addition, while **sustainability legislations** are essential for the protection of the environment and human health, the current regulatory set-up of EU sustainability legislations imposes a cumulative burden, contradictory demands and uncertainty that risks weakening the competitiveness and innovative capacity of the EU pharmaceutical industry. For instance, several proposed or implemented sustainability legislations including GHG reduction targets, the proposed universal restriction on PFAS, and the Urban Wastewater Treatment Directive (UWWD) significantly increase compliance costs for pharmaceutical companies. Moreover, uncertainty about their exact implementation and lack of coordination between health and environmental regulation hamper innovation activity and may divert resources away from innovation. More clarity and coordination of these legislations with other sectoral policies are therefore needed.

The **AI Act** aims to ensure the safe and trustworthy development and use of artificial intelligence in the EU by introducing a risk-based regulatory framework. The Act protects innovation capacity in pharmaceutical development by exempting AI models used solely for pharmaceutical R&D from high-risk regulatory requirements and by supporting safe experimentation through regulatory sandboxes. However, innovation in medical devices may still be hindered, due to misalignments between the AI Act and the MDR/IVDR.

1) Horgan et al. (2022), European Health Data Space – An opportunity Now to Grasp the Future of Data-Driven Healthcare, see link. / 2) MedTech Europe (2024), MedTech Europe IVDR & MDR Survey and Results 2024 – Public Report December 2024, see link, and interviews by Copenhagen Economics with selected EUCOPE members.

Cost of compliance and complexity have increased, and the regulations are not likely to close the international competitiveness gap

In the case of the **Critical Medicines Act (CMA)**, the incentive-based provisions to increase manufacturing capacity in the EU and strengthen security of supply for Critical Medicines may strengthen EU manufacturers' competitiveness vis-à-vis China or India, or reinforce local production capacity, especially for critical medicines such as generics and off-patent medicines. Nevertheless, the absence of a thorough assessment of the potential impact of collaborative procurement, combined with the possibility of a broad definition of "medicines of common interest", introduces uncertainty that could dampen overall investment incentives.

Cost of compliance and complexity have substantially increased through the legislations

The legislations in focus have significantly increased the complexity of the regulatory landscape, thereby raising the cost of compliance for companies operating in the life sciences sector.

Monitoring and documentation requirements have expanded under the CTR, the GMO Directives, the AI Act and the MDR/IVDR Regulations, and are expected to grow further under the European Health Data Space (EHDS) Regulation. In parallel, the EU's sustainability agenda introduces extensive new environmental reporting obligations, placing additional strain on company resources.

Despite their stated aim of harmonisation, the CTR and the HTA Regulation are unlikely to substantially reduce compliance burdens. Duplication risks between EU-level and national processes persist, and the Clinical Trials Information System (CTIS) remains difficult to navigate. As a result, administrative efficiencies remain elusive.

In the short term, the rising compliance burden forces companies to reallocate internal resources from innovation-oriented activities to regulatory tasks. Over the longer term, firms may need to expand their compliance teams, further increasing operational costs. This burden will be particularly felt by small and mid-sized biopharmaceutical firms.

Beyond the growing volume of reporting and documentation, the above-mentioned inconsistencies and overlaps between legislative instruments – both in substance and in timing – create a fragmented and uncertain regulatory environment. This complexity is exacerbated by the involvement of multiple regulatory bodies in similar processes, which can lead to conflicting interpretations or decisions, e.g. the overlapping frameworks of the GMO Directives and the MDR regulation, or the opposing national requirements under the CTR. The result is reduced predictability for companies and a more challenging pathway for bringing innovations to market.

Since the foreseen Biotech Act includes provisions aimed at regulatory simplification, it remains to be seen whether the Act can markedly improve upon the current situation and reduce compliance cost. However, it appears unlikely that policymakers will re-open recently enacted regulations to retroactively apply these simplification principles more broadly.

As a result, the EU may not close the widening international competitiveness gap

International competitiveness refers to the ability of EU-based companies to compete successfully in global markets in terms of innovation, investment, and market share. We also assess the international competitiveness of the EU regulatory framework itself – that is, its attractiveness as a location for developing and launching innovative medicines and medical devices. This attractiveness encourages EU-based companies to retain a significant portion of their operations in the EU, while also drawing non-EU companies to invest, develop and launch their products in the EU, ultimately benefitting both the EU economy and patients.

Naturally, the impact of legislation on international competitiveness is closely linked to its effects on innovation capacity and compliance burdens in comparison to regulatory environments in other parts of the world.

Overall, we find that the current legislative landscape, taken as a whole, is not sufficient to close the widening international competitiveness gap. In fact, the existing regulatory framework may be reinforcing negative trends: for example, between 2018 and 2022, R&D spending in China grew at more than three times the rate of the EU, and since 2020, global CAR-T clinical trials have nearly tripled—yet only 2 in 10 take place in the EU.[1]

While the streamlined regulatory processes and enhanced scientific support for smaller companies foreseen in the **EU General Pharmaceutical Legislation** may make the EU a more attractive place to develop and launch in, the potential negative effects of a baseline reduction of RDP/MP and a complex modulation system may affect the attractiveness of the EU market such that the net effect on international competitiveness is negative.

The harmonisation of previously fragmented systems through the **CTR and the HTA Regulation** is intended to enhance the EU's attractiveness as a location for clinical trials and product launches. However, continued duplication and burdensome procedures risk limiting these benefits. It is also important to note that the EU's attractiveness as a market to conduct clinical trials and launch in is influenced by a wide range of factors, many of which fall outside the scope of these regulations.

1) EFPIA (2025), EU Pharmaceutical Legislation, see link.

Although not intended, many regulations affect market access negatively

By contrast, regulations such as the **MDR/IVDR, the GMO Directives, and the AI Act** impose stricter rules and more onerous documentation requirements than those seen in other jurisdictions, such as the US. Since the introduction of the MDR and IVDR in 2017, the medical devices sector has experienced a marked decline in the number of manufacturers choosing the EU as the first market in which to launch medical and in-vitro diagnostic devices.[1] For example, the share of small medical device developers wanting to launch first in the EU has dropped from 77% to 58% since the introduction of the MDR.[1]

In the case of advanced therapy medicinal products (ATMPs), the EU requirement for a GMO risk assessment prior to clinical trials makes the EU a less attractive destination for development compared to the US, where such a requirement does not exist.[2] Some companies have reported choosing not to develop certain products in the EU specifically due to these GMO regulations. Overall, the EU risks being perceived as a more complex and slower environment for innovation – particularly where legislation is seen as excessively stringent, misaligned, or inconsistently implemented.

The **stringent and multiple environmental legislations** in the EU add to the overall system complexity and are costly to observe, thereby risking to dissuade development of medicinal products in the EU.

The two legislations expected to boost international competitiveness are the **EHDS Regulation and the Biotech Act**. Access to large amounts of electronic health data, through the EHDS, could put companies already conducting R&D in the EU at a competitive advantage and attract more R&D investment to the EU. Its success however depends on harmonised implementation of the rules by member states. The Biotech Act is strongly focused on the EU's ability to translate research into innovation. If sufficiently ambitious, it can strengthen the EU R&D ecosystem and translational outcomes, thereby improving competitiveness similar to highly effective US clusters.

Given current legislations, speed of market access will likely not improve

We also assessed the likely impact of the legislations on market access and specifically, whether they affect the speed at which companies' innovations can reach the market, the complexity of market access processes, or the expected revenues at launch. These factors, in turn, influence companies' incentives to prioritise launching in Europe.

We find that the legislations can be grouped into three categories based on their objectives and anticipated effects.

The **first group** – comprising the EU HTA Regulation, the EU GPL, and the CMA – explicitly aims to improve and accelerate market access procedures across the EU. However, the provisions currently envisaged under these regulations raise doubts about their ability to deliver on this ambition, and we therefore assess their likely impact as ambiguous.

In theory, the **EU HTA Regulation** could accelerate patient access by improving timelines in Member States with less developed HTA systems, harmonising previously fragmented assessments, and clarifying evidence requirements early via JSC. However, the risk of national follow-up reviews and the limited availability of JSCs could undermine these benefits. Companies have also raised concerns that the Regulation may not improve access for orphan medicines, as it does not provide for a dedicated JCA with more flexible data requirements.

While the shorter regulatory timelines proposed under the European Commission's proposal for the **EU GPL** may, in principle, accelerate market entry for medicines, the legislation lacks effective provisions to address the root causes of access delays in the EU. Moreover, these shorter marketing authorisation timelines are not included in the Council's position. This can be seen a missed opportunity.

The **CMA** could improve availability by addressing medicine shortages and ensuring more reliable supply of critical medicines, through revised procurement criteria and related measures. At the same time, the CMA proposes collaborative procurements to improves access to other medicinal products of common interest. However, it is important to distinguish between these two categories.

For critical medicines, shortages are often driven by supply disruptions. The CMA does address some root causes of these disruptions, for example by encouraging EU-based production. In contrast, unavailability of medicinal products of common interest is typically not due to supply disruptions but rather access and procurement-related factors, such as pricing mechanisms. These underlying issues/barriers are not addressed in the CMA. Additionally, the effects of the proposed collaborative procurement framework on both speed and revenue potential remain unclear.

1) MedTech Europe (2024), MedTech Europe IVDR & MDR Survey and Results 2024 – Public Report December 2024, see link. / 2) Tajima et al. (2022), Impact of genetically modified organism requirements on gene therapy development in the EU, Japan, and the US, see link.

Life sciences competitiveness also hinges on market access conditions

The **second group** – including the MDR/ IVDR, the AI Act, and the GMO Directives – is primarily focused on safety, and individually or collectively appears to extend the time to market for medical devices and ATMPs. The approval process introduced by the **MDR/IVDR** has led to longer timelines, delaying access for innovative (in vitro) medical devices. The additional documentation requirements imposed by the AI Act, when layered onto MDR obligations, may result in companies prioritising non-EU markets for device launches, potentially delaying access for EU patients.[1] Moreover, the fragmented implementation of the GMO Directives across Member States delays the granting of manufacturing authorisations and the initiation of clinical trials by up to 12 months, thereby hindering timely access to market for ATMPs.[2]

The **third group** – comprising the CTR and EHDS Regulations – could positively impact time to market, depending on how they are implemented. By facilitating an increase in the number of clinical trials conducted in the EU, the **CTR** has the potential to accelerate access to innovative treatments and expand the number of patients who benefit from them. However, it is too early to determine whether this outcome will materialise. Much will depend on whether the harmonisation of clinical trial requirements can overcome the persistence of additional national-level requirements. The **EHDS Regulation** could directly support faster market access by improving the availability and quality of real-world data for regulatory and HTA decision-making. Access to standardised, cross-border health data supports the generation of real-world evidence (RWE), which strengthens pharmacovigilance and enables more patient-centric research. This could lead to quicker and better-informed decisions on approval and reimbursement, provided the EU HTA framework recognises RWE as valid clinical evidence.

Ultimately, the EU life sciences sector competitiveness also hinges on market access conditions

Ultimately, the competitiveness of the EU life sciences sector depends not only on the broader regulatory environment, but also on how medicines are priced, accessed, and procured across Member States. The sector's ability to innovate is closely linked to its capacity to commercialise innovations - i.e., to generate revenue once new technologies reach the market. Therefore, the speed and predictability of access and reimbursement for innovative medicines are not merely matters of equity; they are key determinants of competitiveness.

Yet, access to medicines across the EU is constrained. In 2024, 48% of innovative medicines were not available to patients. This share has remained stable since 2019, where 46% of innovative medicines were unavailable.[3] Many barriers exist that delay or prevent patient access, varying widely between Member States. These barriers - ranging from misalignment on evidence requirements and the speed of national timelines to insufficient budgets for implementation and multilayered decision-making processes - have contributed to growing disparities in availability.[3] While the Transparency Directive (Directive 89/105/EEC)[4] sets a maximum 180-day timeline for pricing and reimbursement decisions, actual timelines often exceed this. In 2024, the average waiting time for access to orphan medicinal products (OMPs) across the EU was 578 days, a full month longer than in 2023.[5]

For small and mid-sized pharmaceutical companies in particular, the current complexity and cost of navigating market access across 27 Member States can act as a significant deterrent to launching products in the EU.[6]

To strengthen competitiveness, EU countries must urgently work toward an access landscape that enables pharmaceutical companies to reach a broad share of the market as swiftly and efficiently as possible. Ensuring that prices reflect the therapeutic value of treatments - and that they adequately reward the investment and risks involved in their development - is essential to sustain innovation.

A report from the European Expert Group on Orphan Drug Incentives highlights that some Member States already employ mechanisms that support earlier and faster access to innovative medicines, particularly in the orphan drug space.[7] These include early access programmes, greater use of real-world evidence in access decisions, and pricing models that closely align price with both the value and evidence profile of a treatment and the payer's ability to pay.

Broader adoption of such approaches across the EU is critical to enhancing the region's competitiveness and attractiveness as a launch market. Conversely, without concrete improvements in access - and without clear signals from Member States that they are committed to delivering innovation to patients - the EU risks weakening incentives for innovation and further undermining the global competitiveness of its life sciences sector.

1) Copenhagen Economics based on interviews with selected EUCOPE members. / 2) ARM, ebe, EFPIA, and EuropaBio (2017), Possible solutions to improve the European regulatory procedures for clinical trials with Advanced Therapy Medicinal Products consisting of or containing Genetically Modified Organisms, see link. / 3) Beattie et al. (2024), Clinical trial applications for investigational medicinal products that contain or consist of genetically modified organisms: industry experiences under the European Union Clinical Trial Regulation (536/2014), *Cell & Gene Therapy Insights 2024;10(6),375-395,* see link. / 4) EUR-Lex (1989), Council Directive 89/105/EEC, see link. / 5) EFPIA (2025), EFPIA Patients W.A.I.T. Indicator 2024 Survey, see link. / 6) WHO (2023), Issues and challenges in access to medicines faces by small countries in the WHO European Region, p. 3, see link. / 7) European Expert Group on Orphan Drug Incentives (2025), An EU Access Toolbox for Orphan Medicinal Products that enables early and equitable access, see link.

ANALYSIS

List of legislations covered

Our framework for assessing impacts on competitiveness and market access

To evaluate the impact of current and future legislations on competitiveness and market access from the perspective of pharmaceutical companies, we have developed a framework based on four dimensions. Competitiveness is assessed across three key areas: capacity to innovate, compliance costs, and international competitiveness - aligned with the European Commission's competitiveness check. Market access is examined as a separate dimension. A detailed description of each dimension is provided below. When assessing the impact along the four dimensions, we focus solely on the impact of regulation all else equal, i.e. as if nothing else changes.

Competitiveness assessment

Capacity to innovative

With capacity to innovate, we are assessing the ability to transform scientific research into market-ready innovations.

Specifically, we are assessing whether a legislation affects one or more of the following:

- Incentives to innovate
  - Intellectual Property Rights
  - Regulatory incentives
- Access to resources
  - Funding
  - Labour
  - Digital infrastructure
- Efficiency of regulatory approval

If one of the above increases, e.g. the efficiency and speed of regulatory approval, we label it as a positive impact on competitiveness and vice versa. If we find both positive and negative effects, we label the impact as unclear/ambiguous.

Cost of compliance

Compliance costs captures the changes in a company's costs related to complying with a regulation.

When assessing the compliance costs, we are focusing on **permanent changes** in compliance costs. We recognise that most regulatory changes will lead to increased compliance costs in the short run as procedures need to be changed and expertise needs to be acquired. In other words, the compliance costs will most likely increase especially for small and mid-sized companies in the short run following new legislations. Examples of such costs include ESG and sustainability compliance or reporting on shortages.

To arrive at a more nuanced and long-term conclusion on the effect on competitiveness, we focus on permanent changes. If the compliance costs permanently decrease, we label it as a positive impact on competitiveness and vice versa. If we find both positive and negative effects, we label the impact as unclear/ ambiguous.

International competitiveness

When assessing international competitiveness, we assess the competitive situation in which the legislation places EU-based companies- compared to companies based in other regions and/or the attractiveness of the European market for investments.[1] In other words, whether the legislation is aligned with global best practices or not.

This is of interest, as a legislation might be a step towards closing a competitiveness gap or increasing the intra-EU competitiveness but might not close the gap to international competitors.

If a legislation closes (part of) the gap to international competitors, we label it as a positive impact on competitiveness and vice versa. If we find both positive and negative effects, we label the impact as unclear/ ambiguous.

Market access

We also assess the effects of a legislation on market access. When assessing the effects on market access we focus on:

- Speed of reaching the market
- Complexity of procedures (divergence)
- Expected return on investment, i.e. effect on prices and/or volume

If a legislation increases the speed/expected return or reduces the complexity, we label it as a positive impact on market access and vice versa. If we find both positive and negative effects, we label the impact as unclear/ ambiguous.

1) We define an EU-based company as a company that carries out key parts of its operations in the EU and is therefore likely to be affected by changes in EU regulations.

Applied legislations

EU Health Technology Assessment (1/3)

Regulation (EU) 2021/2282[1] and Implementing Regulation (EU) 2024/1381[2]

Description

Problem

Health technology assessments (HTAs) across EU Member States are fragmented, with differing procedures and evidence requirements. Undergoing the HTA process in multiple Member States is a resource-intensive and administratively burdensome process for marketing authorisation holders, such as pharmaceutical companies. As a result, manufacturers may prioritise certain markets over others, leading to delays and inequities in patient access across the EU.

- The time between marketing authorisation and the date a medicine becomes available to patients ranges from 128 days (Germany) to 840 days (Portugal) across the EU.[3]

Objective

The EU HTA Regulation aims to harmonise and streamline HTA across EU Member States. Its main objectives are:[4]

- **Enhance access**: Support faster and more equitable access to effective health technologies for patients across the EU.
- **Ensure efficient use of resources**: Avoid repeated clinical assessments of the same health technology in different Member States.
- **Ensure high-quality evidence**: Promote the use of robust, evidence-based assessments to support national decision-making on pricing and reimbursement.
- **Support innovation**: Provide more predictable and transparent processes that facilitate innovation and investment in health technologies.

To achieve these objectives, the following provisions are being/will be implemented:

- **Joint Clinical Assessment (JCA)**: The clinical effectiveness and safety of new technologies are assessed jointly at the EU level. Member States are required to take JCAs into account in their national HTA processes, thereby reducing duplication and promoting consistent evaluation standards. Member States still have the possibility to add evidence requirements in addition to those stated in the JCA.
- **Joint Scientific Consultations (JSCs):** Health technology developers can engage in JSCs with the Coordination Group to receive guidance on evidence generation plans.
- **Common methodologies and procedures:** The regulation mandates the development and application of common methodologies, procedures, and tools for HTA across the EU.
- **Member State Coordination Group on HTA:** A Coordination Group composed of representatives from Member States' HTA authorities is responsible for overseeing joint clinical assessments, joint scientific consultations, and the identification of emerging health technologies.
- **Timing**: The JCA process begins in parallel with the EMA's marketing authorisation assessment, to ensure that HTA bodies have the clinical evidence ready for evaluation when the product is approved.

Implementing Regulation (EU) 2024/1381 provides detailed procedural rules for conducting joint clinical assessments.

- EC SME test: Yes[5]
- EC Competitiveness check: No

Overall competitiveness assessment

The EU HTA Regulation aims to harmonise evidence requirements, streamline processes, and support faster market access across Member States. However, without careful implementation, it risks consolidating diverse national demands into a single process. What were once parallel national procedures may now become a front-loaded, resource-intensive exercise - particularly challenging for small and medium-sized developers. Rising compliance costs and the diversion of resources from innovation to evidence generation could ultimately undermine the Regulations intended positive effect on competitiveness.

1) EUR-Lex (2021), Regulation (EU) 2021/2282, see link. / 2) EUR-Lex (2024), Commission Implementing Regulation (EU) 2024/1381, see link. / 3) EFPIA (2025), EFPIA Patients W.A.I.T. Indicator 2024 Survey, see link. / 4) According to the proposal of the EU HTA Regulation COM(2018) 51 final, see link. / 5) A description of the likely impacts on SMEs is included in the inception impact assessment, see link.

EU Health Technology Assessment (2/3)

Competitiveness assessment

Capacity to innovate

While the EU HTA is intended to reduce duplication and harmonise Member States requirements, it risks combining previously separate national procedures into one resource-intensive process under tight timelines. This may put a strain on companies thereby diverting resources away from innovation.
(+) The harmonisation of the EU HTA will increase regulatory efficiency and thereby enhance capacity to innovate, a critical improvement. 37 per cent of respondents in the public consultation for the impact assessment indicated that the current fragmented system decreases incentives for innovation.[1]
(-) The possibility of requesting multiple PICO[2] surveys across Member States combined with a 90-day deadline to develop and submit the JCA dossier means that companies need to develop capabilities for simultaneous (instead of previously sequential) HTA submissions to manage complex evidence requirements across multiple PICO frameworks. This may put a strain particularly on small and mid-sized companies and divert resources away from innovation.
(-) Limited opportunities for engagement in JSCs reduce possibilities for structured interactions with the assessors. This lack of early dialogue increases the risk that companies' evidence generation strategies will be misaligned with assessor expectations, which may in turn hamper regulatory efficiency and weaken the sectors' capacity to innovate. The importance of early scientific advice is shown by EMA data: a 2020 paper showed that the success rate of applications who received and followed early scientific advice were was double compared to applications that did not.[3]
(-) The fact that the EU JCA outcome is not binding for Member States may mean continued fragmentation of clinical assessments of the EU if Member States continue to conduct their own reviews and require extra data. How disciplined Member States will be in aligning to the EU JCA and not add further requirements remains to be seen.

Cost of compliance

The net impact of the EU HTA on compliance remains unclear and will depend on its implementation. There is a risk that what was previously a set of parallel HTA processes may now become a single, resource-intensive exercise, or that the EU HTA will be supplemented with additional national requirements in Member States. Should this be the case, compliance costs will not be reduced, but rather front-loaded and aggregated, or even increased.
(+) The submission of a single dossier for HTA assessment at the EU level has the potential to reduce administrative costs associated with multiple national HTAs. According to the impact assessment of the Regulation, 70 per cent savings could be realised when replacing national HTA submission with one single EU HTA submission.[4]
(+) / (-) Currently, the cost of the JSC is funded through the EU4Health, which removes barriers to participation for companies.[5] However, by 2028, the Commission is to consider whether there is a need to introduce a fee-paying mechanism.[6] If such a fee-paying mechanism is introduced, it will increase the cost of compliance, and it may also reduce the incentives to launch in the EU and comply with necessary requirements, as it becomes more difficult to access the JSCs.
(-) The possibility for national assessments being required *in addition* to the EU HTA creates an extra burden for the companies.
(-) The EU HTA introduces expanded evidence expectations. Broader comparator analyses, additional subgroup analyses, longer follow-ups on survival data and stricter methodological standards will contribute to increased compliance costs.
(-) Limited interactions between assessors and companies in the scoping phase, combined with short procedural timelines, will disproportionally affect small and mid-sized companies, which often lack capacity to manage short submission and reply deadlines.[7]

1) European Commission (2018), Impact Assessment – Strengthening of the EU Cooperation on Health Technology Assessment (HTA), see link. / 2) PICO (Population, Intervention, Comparator, Outcome) is a framework used to define the key elements of a clinical question or evidence requirement in HTAs, clinical research, and systematic reviews. It ensures that assessments are focused, relevant, and comparable. / 3) Ofori-Asenso et al. (2020), Improving Interactions Between Health Technology Assessment Bodies and Regulatory Agencies: A Systematic Review and Cross-Sectional Survey on Processes, Progress, Outcomes, and Challenges, *Front Med (Lausanne). 2020 Oct 16;7:582634,* see link. / 4) European Commission (2016), Inception Impact Assessment, p. 9, see link. / 5) European Commission (2025), From theory to practice: implementing the EU Health Technology Assessment Regulation, see link. / 6) EUR-Lex (2021), Regulation (EU) 2021/2282, see link. / 7) EUCOPE (2024), Joint Industry Statement: Life science industry concerns over the workability of EU HTA, see link.

EU Health Technology Assessment (3/3)

Competitiveness assessment

International competitiveness

The EU HTA can affect international competitiveness both positively and negatively, resulting in an overall unclear impact on competitiveness.
(+) The EU HTA aims to adopt methodological guidance that follows international standards of evidence-based medicine. This could contribute to a level playing field for companies operating in the EU internal market. Faster access to the market and a more harmonised process may also make the EU a more attractive market in which to invest and launch in.
(-) Expanded evidence expectations and requirements (multiple PICOs) can make companies prioritise regulatory approval and reimbursement in faster-moving markets (e.g., the US and Japan). This trend is highlighted by data showing that between January 2021 and June 2023, EMA marketing authorisation approval was delayed by 327 and 214 days compared to the US and Japan, respectively.[1]

Market access

In theory, the EU HTA provisions could accelerate patient access across Member States, by accelerating access in countries with less developed HTA systems, harmonising previously separate reviews and clarifying evidence requirements early through JSCs. However, the above-mentioned risk of national follow-up reviews and limited possibility for JSC can undermine the speed benefit. Companies also express concern that the regulation will not bring orphan medicines faster to the market, as the regulation does not foresee an orphan-specific JCA with more flexibility on data requirements.

1) CRA for EFPIA (2024), European Access Hurdles Portal: Results from the second year of data collection, p. 9, see link.

Companies' perspectives on the EU Health Technology Assessment

The JCA starts off with a scoping phase where pharmaceutical companies learn the specific evidence requirements for their JCA. Based on submitted EMA applications material, the HTA assessors prepare assessment PICOs. Each Member State completes PICO surveys to identify national evidence needs, and this creates a comprehensive but also complex set of requirements that companies must address. Following PICO consolidation and validation, the finalised assessment scope is communicated to the applicant company. The company then has 90 days to develop and submit the JCA dossier. This timeline is strict and requires advanced preparation and robust evidence generation capabilities to ensure timely, comprehensive submissions. Smaller companies often do not have the required resources and are therefore risk not being able to deliver high-quality input into the JCA in time.

For orphan medicines, the EU HTA presents unique challenges. The stringent requirements might make it more difficult for these medicines to get a positive outcome of the JCA, which could limit their availability to patients with rare diseases.

The increased compliance costs associated with the EU HTA are a significant concern, especially for smaller companies. These costs could hinder their ability to compete, ultimately affecting market dynamics and innovation.

Clinical Trials Regulation (1/3)

Regulation (EU) No 536/2014

Description

Problem

The Clinical Trials Directive from 2001 brought important improvements in the safety and ethical soundness of clinical trials in the EU. However, it also led to fragmented clinical trial activities across EU Member States, creating complexity for multinational trials and undermining the EU's competitiveness in clinical research. This might have contributed to a decline in clinical trial activity in the EU compared to global competitors, potentially limiting patient access to innovative treatments and threatening the EU's competitive position.

- The European Economic Area (EEA) accounted for 9 per cent of clinical trials globally in 2023 – a decline from 18 per cent in 2013. This drop reflects a relatively stable number of clinical trials initiated in the EEA over the period, while the number of clinical trials globally increased. Therefore, the EEA captured a lower share.[1]
- The declining global share of clinical trials may by driven by longer trial timelines. Site start-up and recruitment are slower in the EEA than in the US.[2]
- Although the number of ATMP developers based in Europe is approximately half of that based in North America, the number of clinical trials that have been initiated in the EU is only about a third of that in North America. Slower time to approval of clinical trials and overlap with the GMO framework are put forward as possible explanations for the EU lagging behind the US in terms of ATMP clinical trials.[3]

Objective

The Clinical Trials Regulation (CTR) aims at harmonising and simplifying clinical trial procedures across the EU through a unified regulatory regime, standardised procedures, and a centralised clinical trials information system (CTIS). It also aims at making it easier for pharmaceutical companies and non-commercial sponsors to conduct multinational clinical trials, which is expected to lead to an increase in the number of studies conducted within the EU.[4,5]

To achieve the objective, the following provisions were/will be implemented:

- **The Clinical Trials Information System** (CTIS) as the single portal for submission of new clinical trials, where clinical trial sponsors are to apply for a clinical trial in all countries of the EEA with one application instead of having to apply separately in every country. This single application is submitted to national competent authorities and to the ethics committees for all involved countries.
- **Standardised assessment procedures** across Member States of clinical trial protocols. However, each Member State has to evaluate the clinical trial application through the system, allowing Member States to add national requirements.
- **Rules on the protection** of subjects and informed consent.
- **Increased transparency** of information on clinical trials.[6]

- EC SME test: No
- EC Competitiveness check: No

Overall competitiveness assessment

Through simplifying and harmonising previously fragmented procedures, the CTR is intended to enable faster and less costly clinical trials in the EU. If fully implemented, it will likely attract more clinical trial activity to the EU and hence more knowledge, information, and collaboration across academia and industry, which can accelerate innovation and thereby enhance competitiveness. However, the risk of added national requirements may undermine this impact. Key implementation challenges such as delays in approvals, inconsistent requirements across Member States, technical issues with the CTIS, and regulatory bottlenecks, further complicate progress. Moreover, the EU system remains slower than those of the US and Japan. Therefore, the CTR, all else equal, reduces the international competitiveness gap but it does not close it, and thus represents a missed opportunity to make the EU more attractive for clinical trials. It is however important to note that various barriers to clinical trial activity in the EU emanate from national policies beyond current EU competences, which the CTR cannot address.

1) EFPIA (2024), Assessing the clinical trial ecosystem in Europe p. 13, see link. The number of clinical trials initiated in the EEA dropped by 446 trials, while the total number of global clinical trials increased by 8,786 trials over the same period. Source: Copenhagen Economics based on numbers reported on p. 13. / 2) EFPIA (2024), Assessing the clinical trial ecosystem in Europe p. 33, see link. / 3) Alliance for Regenerative Medicine (2019), Clinical Trials In Europe: Recent Trends in ATMP Development, see link. / 4) European Commission (2025), Clinical Trials – Regulation EU No 536/2014, see link. / 5) EUR-Lex (2025), Clinical trials – Regulation EU No 536/2024, see link. / 6) EMA (2025), Clinical Trials Regulation, see link.

Clinical Trials Regulation (2/3)

Competitiveness assessment	**Capacity to innovate**	The CTR, along with the now implemented CTIS, has the potential to increase capacity to innovate through more simple and harmonised clinical trials procedures and enhanced data transparency. However, this effect may be dampened by the risk of Member States adding national requirements. **(+)** A single submission under consistent rules paired with a coordinated procedure and streamlined documentation can simplify multinational clinical trials submissions in the EU, thus incentivising sponsors to conduct clinical trials in the EU and ultimately increase the number of studies conducted within the EU.[1] **(+)** Standardised procedures can reduce the administrative burden for innovative research.[1] **(-)** Member States can add national requirements including supplementary documents. This undermines the aim of the Regulation, as national requirements go against a harmonised process across the EU.[2] **(-)** Experiences from companies indicate that the lack of harmonised implementation of the CTR, particularly the role of the Reporting Member State (RMS), has resulted in a slower and more complicated process than intended.[3] The RMS is meant to centralise and streamline Requests for Information (RFIs), but in practice, the process is fragmented and slow. RFIs are often related to administrative or 'minor' topics, causing approval delays, while a focus on trial risk/benefit of participant safety would be more useful.[4] The unclear role of RMS also leads to poor coordination between regulatory and ethical reviews, causing rework, delays, and added burden for sponsors and sites.[4] **(-)** Companies describe the CTIS as failing to meet its aim of being 'harmonised and simplified'. Only the initial uploading of documents is a harmonised experienced. Following this, individual Member State requirements are fragmented, often generating a lack of consistency on requirements, see the case studies on page 23. These national requirements increase the regulatory burden and hinder the capacity to innovate.[3] **(-)** Technical issues require sponsors to spend resources on dealing with these issues and divert time and attention away from more value-adding activities. The CTIS issues are summarised in frequently updated documents on the CTIS "List of known issues of Sponsor Users and authorities".[3,5,6] **(-)** The current lack of integration of ethics committees affects the harmonised experience in the administration of trials in the EU. The CTR recognises the independence of national ethics committees; however, this leads to a lack of harmonised or predictable decision making that hampers the effectiveness of clinical trials procedures.[7]	
	Cost of compliance	**(+)** In the long run, the CTR is expected to contribute positively to European competitiveness by reducing compliance costs through the centralisation of clinical trial applications via a single EU portal. **(-)** However, if Member States introduce additional national requirements, this will increase administrative complexity and associated costs, thereby dampening the potential positive effect. For example, one study reports that Ireland requires searchable documents without signatures and not scanned documents. Italy, on the other hand, requires scanned documents with (ink) signatures.[3] **(-)** A study reports that the burden on applicants has increased overall, mainly due to increased documentation requirements, see also the case study on page 21.[3]	

1) European Commission (2025), Clinical Trials – Regulation EU No 536/2014, see link. / 2) EFPIA (2024), Assessing the clinical trial ecosystem in Europe, see link. / 3) Patrick-Brown et al. (2024), Experiences and challenges with the new European Clinical Trials Regulation, *Trials 25,* see link. / 4) Center for Vaccinology Ghent (CEVAC) & Center for the Evaluation of Vaccination Antwerp (CEV) (2024), The Impact of EU-CTR: An emergency signal from 2 large academic vaccine trial centers in Belgium, see link. / 5) EMA (May 2025a), Clinical Trials Information System (CTIS) List of known issues for Sponsor Users, see link. / 6) EMA (2025b), Clinical Trials Information System (CTIS) List of known issues for Member State, European Commission or EMA users, see link. / 7) EFPIA (2025), Improving EU Clinical Trials: Proposals to Overcome Current Challenges and Strengthen the Ecosystem, see link.

Clinical Trials Regulation (3/3)

Competitiveness assessment	**International competitiveness**	The attractiveness of the EU as a location to conduct clinical trials depends on several factors, including trial costs, patient recruitment timelines, site start-up timelines, and overall healthcare system infrastructure. Any harmonisation achieved by the CTR is therefore just one factor out of many determining the attractiveness of Europe for clinical trials. Despite the harmonisation efforts of the CTR, the approval system is still slower than the US system, and the CTR therefore reduces the international competitiveness gap, but it does not close it. Companies express that the EU remains attractive for clinical trials due to the relatively low cost of conducting clinical trials in the EU. However, fees differ across countries. A study has found discrepancies in the fee structure, ranging from EUR 1,321 to EUR 17,000.[2] **(+)** Once technical issues of the CTIS are resolved, it has the potential to become a more efficient submission system. A more efficient system should increase the EU's competitiveness as the simplified and harmonised submission system reduces the administrative burden and makes it easier to recruit patients and obtain approvals for multinational trials. **(-)** Even with standardised procedures, the EU approval system will be slower or at best on par with other regions. The CTIS timeline is 60 days for initial application, which can be extended to 106 days.[1,2] This is significantly longer than the timelines of other regions, e.g. US FDA: 30 days, Japan: 30 days, and China: 60 days.[3,4] Additionally, companies note that the centralised systems in the US and Japan make these countries more attractive for clinical trials. This is confirmed by two large vaccine trial centres in Belgium. They experience reduced attractiveness of initiating studies in Europe, and for 40% of studies that they were not selected for, sponsors stated that it was due to concerns about the CTR.[2]
	Market access	The CTR has the potential to improve market access. It is currently too early to determine whether the CTR is leading to an increase in clinical trials in EU. If it does, improved patient access through clinical trials may accelerate market entry. Additionally, faster trial execution could further shorten time to market. Therefore, the CTR may contribute to improved market access, but this depends on whether harmonisation will eventually prevail over the temptation for Member States to add additional requirements.

1) EMA (2025), CTIS Evaluation Timelines, see link. / 2) Center for Vaccinology Ghent (CEVAC) & Center for the Evaluation of Vaccination Antwerp (CEV) (2024), The Impact of EU-CTR: An emergency signal from 2 large academic vaccine trial centers in Belgium, see link. / 3) FDA (2024), Investigational New Drug (IND) Application, see link. / 4) Clinical Leader (2023), 5 Reasons Why APAC Leads The World In Clinical Trials, see link.

Perspectives on the Clinical Trials Regulation

Case study

Company perspective

The introduction of the EU Clinical Trials Regulation (CTR) aimed to streamline the clinical trial application process across Europe through a single submission portal and a unified review process. However, the practical implementation of the CTR has revealed several ongoing challenges that affect the efficiency and predictability of clinical trial initiation in the region.

A key issue is the decentralised nature of the European regulatory system. Although the CTR was designed to centralise and harmonise the review process, each country's regulatory agency still has a strong national review process, which complicates the centralised approach intended by the CTR. As a result, the reporting Member State responsible for the review is not fully taking responsibility for harmonising the questions and requests. This leads to each country making its own full review, which can result in frustration and delays in starting trials.

This situation introduces additional complexity and uncertainty for clinical trial sponsors. We [the EU] should be striving for more certainty in terms of time to start trials, as time to trial start is a key metric for companies and investors. When processes and timelines vary across Member States, it becomes more challenging for sponsors to plan and initiate studies efficiently.

Despite these challenges, Europe remains an attractive location for clinical trials, in part due to lower costs compared to the US. However, the burdensome nature of the process and the need for a more centralised approach are missed opportunities to make Europe more attractive for clinical trials.

Source: Copenhagen Economics based on interview with a pharmaceutical company.

Case study based on Patrick-Brown et al. (2024)

While approval timelines have improved compared to the previous Voluntary Harmonisation Procedure (VHP) - from a median of 158 days to between 46 and 80 days depending on trial type - these gains are insufficient in the context of fast-moving outbreaks. For instance, MOSAIC, a low-intervention trial during the mpox outbreak, still faced median approval times of over 46 days, while observational arms in non-CTIS countries were approved in as little as 13 days.

Administrative burdens have increased dramatically. Where previous submissions required fewer than 200 documents, trials under CTIS have involved between 329 and 800 documents, even for relatively simple amendments. Much of this is due to added national-level demands and inflexible rules requiring extensive legal and procedural documentation, even for publicly funded, non-commercial studies.

Furthermore, the CTIS system suffers from rigid procedures and technical flaws. National authorities often impose inconsistent document requirements, with extremely short and varying deadlines for requests for information. Missing these can invalidate approval in an entire country.

These problems have ethical implications, as unnecessary delays risk compromising the value and feasibility of trials. While the centralised system was meant to simplify the process, it has instead created a heavier burden, especially for academic sponsors. To restore its intended function, reforms are urgently needed - particularly more flexibility in amendments, harmonisation of national requirements, and technical fixes to CTIS. Without these, the regulation continues to obstruct rather than enable timely clinical research.

Source: Copenhagen Economics based on Patrick-Brown et al. (2024), see link.

Medical Device Regulation & In Vitro Diagnostics Regulation (1/2)

Regulation (EU) 2017/745 & Regulation (EU) 2017/746

Description

Problem

Medical devices and in vitro diagnostic devices are invented and developed at a fast-moving pace, and the previous directives were no longer adequate to address this. Additionally, fragmented national regulations, and a lack of transparency and traceability throughout the device's life cycle, led to safety concerns to the detriment of patient health and safety.[1,2]

- Under the Medical Device Directive (MDD), various scandals cast doubt on the efficacy of the regulatory framework in ensuring patient safety. An often-mentioned scandal highlighting the problems under the MDD is the Poly Implant Prothèse (PIP) scandal, in which a company used industrial-grade silicone instead of medical-grade silicone between 2001-2010.[3,4]

Objective

The Medical Device Regulation (MDR) and In Vitro Diagnostics Regulation (IVDR) aim to improve patient safety and ensure that new devices benefit patients. They aim to enhance the transparency of information and the traceability of devices to facilitate rapid response to safety issues. Additionally, the regulations aim to foster innovation by harmonising regulations across the EU and establishing a robust, transparent, and predictable regulatory framework. The regulations recognise the need to balance stringent safety requirements with the need to foster innovation.

Key provisions include:

- **Reinforcing the supervision of notified bodies**. A notified body is an independent organisation designated by an EU Member State to assess whether certain products conform to the relevant regulations before being placed on the market. With the MDR and IVDR, the supervision of the notified bodies was reinforced and strengthened.
- **Implementing a risk-based classification system of devices**. Devices are classified by intended purpose and inherent risk. The higher the risk, the more regulatory requirements.
- **Establishing mandatory clinical evidence** demonstrating safety and performance, especially for high-risk devices.
- **Implementing a Unique Device Identification (UDI) system** linked to the EUDAMED database to be able to trace a device throughout its supply chain. The expanded EUDAMED database enhances transparency and access to information for patients and healthcare professionals, containing detailed information about devices, clinical investigations, post-market surveillance, and vigilance data.[5]

- EC SME test: No
- EC Competitiveness check: No

Overall competitiveness assessment

The Medical Device Regulation (MDR) and In Vitro Diagnostics Regulation (IVDR) are necessary to ensure patient health and safety. However, strict documentation requirements such as technical documentation, Quality Management System (QMS) documentation, Technical Document Assessment (TDA) documents, and clinical evidence, have made the regulatory process slower, more costly, and more complex compared to the previous Directives. In addition, a lack of alignment among notified bodies on practices and fees, and increased compliance costs have made the EU a less attractive market for launching innovative (in vitro) medical devices. All in all, this places the EU at a competitive disadvantage compared to other regions.

1) EUR-Lex (2025), Regulation (EU) 2017/745, see link. / 2) EUR-Lex (2025), Regulation (EU) 2017/746, see link. / 3) MedTech Europe (2023), The Future of Europe's Medical Technology Regulations, see link. / 3) Svempe, L. (2024), Exploring Impediments Imposed by the Medical Device Regulation EU 2017/745 on Software as a Medical Device, *JMIR Med Inform. 2024 Sep 5;12:e58080,* see link. / 4) MedTech Europe (2015), PIP: Never again, see link. / 5) European Commission (2025), EUDAMED – Overview, see link.

Medical Device Regulation & In Vitro Diagnostics Regulation (2/2)

Competitiveness assessment	**Capacity to innovate**	The MDR and IVDR have created slower and more uncertain regulatory processes, which in turn decreases companies' capacity to innovate, which is essential for meeting the unmet needs of patients. **(-)** Implementation of (stricter) documentation requirements such as technical documentation, Quality Management System (QMS) documentation, Technical Document Assessment (TDA) documents and clinical evidence has made the regulatory process slower compared to the previous Directives due to the more complex certification process. The total average time to complete either the QMS certifications or TDA certification for IVDR is 18 months. For MDR, the certification timeline is 19.6-22 months.[1,2] Companies report that the timelines were 6-12 months prior to the introduction of the MDR and IVDR. A slower regulatory process undermines patient access, innovation, investor confidence, and resilience of health systems. **(+)** However, one study reports that higher costs may lead to innovation. If companies are forced to increase product prices due to new legislative requirements, they will likely look to innovate the product itself to make the price increase acceptable to users. New, safer medical devices will have a competitive advantage over products from markets where the conditions for product development are not so strict.[3] **(-)** The notified bodies are not aligned in terms of practices and fees. Companies report unclear clinical expectations, extensive document requirements, and varying interpretations of compliance standards, all of which hamper innovation due to uncertainty and lack of transparency.[1,2] The unclear expectations also hampers innovation and, in turn, the development of digital health solutions that support care teams in overburdened health system to the detriment of both patients and health systems.[2]
	Cost of compliance	With more regulation and documentation requirements, compliance costs have increased across all MD and IVD manufacturers: **(-)** The MDR/IVDR has significantly increased compliance costs (by up to 100% compared to the previous Directives) due to expanded documentation requirements.[2] The increased costs disproportionally affect small and mid-sized companies, as they represent a relatively larger share of their total expenses compared to larger companies. **(-)** Companies report that the cost of compliance has increased not only due to higher fees but also because of the need to hire new, specialised staff.
	International competiti-veness	The cost of compliance and regulatory uncertainty have made the EU a less favourable market to launch in, and this leads to a decline in international competitiveness. **(-)** Since the IVDR entered into force, only 45 per cent of large IVD manufacturers and 80 per cent of SME IVD manufacturers have chosen the EU as their first launch geography. This is a decrease from 85 per cent and 92 per cent, respectively, before the IVDR came into force.[2] **(-)** Since the MDR entered into force, only 39 per cent of large MD manufacturers and 58 per cent of SME MD manufacturers have chosen the EU as their first launch geography. This is a decrease from 72 per cent and 77 per cent, respectively, before the MDR came into force.[2]
Market access		The approval process set out by the Regulations has led to longer approval timelines, which has slowed down market access of innovative (in vitro) medical devices.[1,2]

1) MedTech Europe (2025), MedTech Europe IVDR & MDR Survey and Results 2024 – Report Highlights, see link. / 2) MedTech Europe (2024), MedTech Europe IVDR & MDR Survey and Results 2024 – Public Report December 2024, see link. / 3) Maresova, P. (2022), Impact of Regulatory Changes on Innovations in the Medical Device Industry, *Int J Health Policy Manag. 2022 Jun 15;12:7262*, see link.

Companies' perspectives on the Medical Device Regulation & In Vitro Diagnostics Regulation

Case study

The introduction of the EU Medical Device Regulation (MDR) was intended to strengthen the safety and performance of medical devices in Europe. However, its implementation has presented significant operational and strategic challenges such as increased bureaucracy, increased costs and up to four times longer certification timelines.

A central aspect of the MDR is the requirement for regular renewals and ongoing surveillance. Companies must undergo renewals every three to five years, along with yearly surveillance audits, which adds significant costs and scrutiny. Unlike medicines, if a device's certificate is not renewed on time, it cannot continue to be placed on the market – not even if the application is pending. This adds complexity and strains the capacity of both notified bodies and manufacturers. It would be sensible to better leverage the yearly surveillance audits and only have a renewal as an exemption based on the surveillance outcomes.

The financial burden associated with MDR compliance has also risen sharply. The costs have increased by up to 100% or in some cases even more. If you look at a company, the fees paid to the notified body have gone up significantly. Additionally, the number of colleagues or service providers needed to handle the increased complexities and timelines has also risen. While I understand the intentions behind the MDR, the process has become more complex and scrutinised.

These regulatory changes have had a direct impact on global market strategies. Before, companies went to Europe to launch first and then to the US. The Medical Device Directive system predictably allowed access to the entire EEA market and Switzerland. That has already flipped under the MDR. The increased complexity and uncertainty in the European regulatory environment have prompted many manufacturers to prioritise launching new devices in other markets, notably the United States.

Artificial Intelligence Act (1/3)

Regulation (EU) 2024/1689[1]

Description

Problem

Artificial intelligence (AI) is a general-purpose technology that brings together data, algorithms, and computing power to enable machines to perform tasks such as reasoning, learning, and decision-making. Its transformative potential in healthcare and life sciences is well recognised. In healthcare, AI can enhance diagnostics, optimise treatment pathways, and improve outcomes; in life sciences, it can accelerate discovery of medicine, reduce development costs, and improve success rates. However, without appropriate regulation, these advances risk reinforcing bias, weakening oversight, and undermining the very trust and safety they aim to enhance.[2]

- The EU healthcare AI market is projected to reach USD 40 billion by 2030, growing at nearly 40 per cent annually.[3]
- 2/3 of European hospitals already use some form of AI.[4]

Objective

The EU AI Act aims to create conditions for the development and use of trustworthy AI systems across the EU. While the Act does not set out sector-specific objectives, its general aims for healthcare and health technology sectors include:

- Establishing clear requirements for AI systems used in clinical and biomedical contexts, in order to minimise risks of harm, ensure accuracy and reliability, and protect patient well-being throughout the lifecycle of AI-driven medical tools, diagnostics, and treatments.
- Preventing discriminatory outcomes and safeguarding privacy and data rights.
- Requiring transparency, traceability, and human oversight for high-risk AI systems used in healthcare and medicine development, to foster public trust and professional confidence in AI-assisted decision-making.

The AI Act also introduces a unified framework to avoid regulatory fragmentation across the EU. If companies do not comply with the regulation, they will face financial penalties of up to EUR 35 million or 7% of total worldwide annual turnover.[5]

Key provisions include:

- **Risk-based classification of AI systems**. Applications used in critical sectors - such as medicine discovery and medical devices - are classified as *high-risk* and are subject to stricter oversight. However, AI systems and models for scientific research and development are exempt from the scope of the Act.[5]
- **Specific obligations** for *high-risk* AI systems such as robust risk management systems; strong data governance and quality controls; transparency and detailed documentation; human oversight to ensure intervention when needed; demonstrated robustness, accuracy, and reliability.
- **Enforcement of the AI Act's provisions through market surveillance** where designated national authorities are responsible for monitoring compliance. They have the power to investigate and issue penalties for non-compliance.
- **Support for innovation through regulatory sandboxes.** The regulation promotes the creation of supervised environments to test and refine AI technologies while ensuring alignment with legal and ethical standards.
- **Establishment of the EU AI Office**, which will coordinate consistent application of the rules across Member States and serve as a central hub for guidance and best practices.

- EC SME test: No
- EC Competitiveness check: No

Overall competitiveness assessment

The AI Act aims to promote innovation through research exemptions, regulatory sandboxes, and a risk-based framework. However, the Act risks increasing compliance burdens, diverting resources from innovation, and placing EU-based companies at a competitive disadvantage for medical device developers. To support healthcare innovation effectively, the Act must ensure proportionality, align with existing frameworks such as the Medical Device Regulation (MDR), and provide clear, practical guidance. A coherent and streamlined approach is essential to prevent duplication and safeguard the EU's leadership in AI and healthcare innovation.

1) EUR-lex (2024), Regulation (EU) 2024/1689, see link. / 2) European Commission (2021), Impact Assessment, SWD(2021) 84 final, see link. / 3) Horizon Grand View Research (2025), Europe AI in Healthcare Market Size & Outlook, 2023-2030, see link. / 4) iQud at LinkedIn, AI Healthcare Impact in Europe (2025), see link. / 5) EU Artificial Intelligence Act, Article 99: Penalties, see link. / 5) EFPIA (2024), EFPIA Statement on the use of AI in medicinal product lifecycle in the context of the AI Act, see link.

Artificial Intelligence Act (2/3)

Competitiveness assessment

Capacity to innovate

The Regulation aims to promote innovation in health technologies by limiting compliance burdens for research despite enforcing a regulation. It does so by excluding scientific R&D from high-risk rules and enabling safe experimentation through regulatory sandboxes. However once products or medical devices are placed on the market or put into service, the exemptions no longer apply.

(+) The regulation provides for *research exemptions* (as described in Recital 25, Articles 2.6 and 2.8) meaning AI-based development tools used in the research and development of medicines and medical devices are exempt from the regulation.[1] This exemption aims to foster capacity to innovate by allowing researchers to experiment with and develop AI technologies without the regulatory constraints that apply to commercial AI applications. For instance, generative AI is already transforming R&D in the life sciences and chemicals industry by enabling "generative design," where foundation models accelerate the creation of new molecules, drugs, and materials.[2]

(-) However, industry is concerned about the uncertainty that remains on the exemption: if an AI tool later moves into clinical use or supports a regulatory decision, it may lose the exemption and trigger full compliance. For innovative therapies, the added uncertainty may further discourage investment in an already high-risk environment.[3]

(+) The establishment of regulatory sandboxes improves regulatory efficiency by providing clear pathways for pharmaceutical companies to demonstrate AI system safety and efficacy before full market deployment. Regulatory sandboxes were first used by the UK's Financial Conduct Authority (FCA) to offer fintechs a controlled testing environment to test their products on a limited set of customers. Such sandboxes benefit regulators by enabling learning, experimentation, and improved policy-making while enhancing engagement with innovators. Regulatory sandboxes enable companies to access markets faster, and they reduce uncertainty by setting clearer regulatory expectations - especially helpful for SMEs and start-ups.[4,5]

(-) Any AI used in diagnostics and other medical devices (i.e. not research and development) will be deemed high-risk under the AI Act. Due to the classification, the companies are required to submit extensive documentation to ensure trustworthy use of AI – in addition to what is required by other legislations. The risk of misalignment with provisions under the MDR/IVDR may delay the development of medical devices.[6] Additionally, the AI Act does not specifically address clinical investigations and performance studies. Therefore, investigational devices (per the MDR) and devices for performance study (per the IVDR) may require an AI Act CE mark before they undergo clinical and performance evaluation.[7] This lack of clarity creates uncertainty and hampers innovation.

1) EFPIA (2024), Statement on the use of AI in the medicinal product lifecycle in the context of the AI Act, see link. / 2) McKinsey (2023), The economic potential of generative AI: The next productivity frontier, see link. / 3) FTI Consulting for EUCOPE (2024), The Economic Lens: Understanding what makes the EU attractive for life science investments, see link. / 4) OECD (2023), Regulatory sandboxes in artificial intelligence, see link. / 5) Cornelli et al. (2023), Regulatory sandboxes and fintech funding: evidence from the UK, *BIS Working Papers No 901*, see link. / 6) EFPIA (2024), EFPIA position on the use of artificial intelligence in the medicinal product lifecycle, see link. / 7) MedTech Europe (2024), Medical technology industry perspective on the final AI Act, see link.

Artificial Intelligence Act (3/3)

Competitiveness assessment	**Cost of compliance**	For pharmaceutical and MedTech companies, most AI applications used in research are exempt from the regulation, hence not implying increased compliance costs. However, companies expect that the AI Act will increase compliance burdens when AI systems transition from research to clinical or commercial applications. Although the creation of the EU AI Office and access to sandboxes will ease implementation, the extensive compliance and documentation effort renders the net effect uncertain. In particular, two issues risk significantly increasing compliance costs: **(-)** First, if the implementation of the AI Act is not harmonised with existing practices, companies risk having to duplicate internal processes. Given that the life sciences industry is already heavily regulated, the implementation of the AI Act should build on established regulatory frameworks such as Good Clinical Practice, pharmacovigilance, and medical device regulations. This avoids duplication of documentation and ensures that documentation and transparency obligations remain proportionate and familiar to developers. **(-)** Second, products that fall simultaneously under the AI Act, the MDR/IVDR and potentially also the European Health Data Space (EHDS) may risk dual compliance requirements, if the regulation is not aligned/ streamlined with already existing regulation.[1] This may affect products such as combination products and digital therapeutics and raises the need for streamlined processes and combined conformity assessments to avoid redundant external reviews and conflicting obligations. Even if the AI Act allows for conformity assessments to be integrated into the MDR/IVDR procedure, this may lead to bottlenecks as few notified bodies are designated for AI compliance and this may delay certification.	
	International competiti-veness	**(-)** Companies experience that the AI Act is giving a competitive edge to companies outside of the EU, e.g. the US and China, as those markets are less regulated than the EU market. The stringent EU regulation may lead companies to launch products outside the EU due to more favourable regulatory environments. However, it is worth noting that the EU may gain a first-mover advantage implementing a regulation that other regions will later adopt like the GDPR. This creates a potential competitive advantage for companies active in the EU.	
Market access		The cumulative documentation requirements imposed by the AI Act on top of the MDR may lead companies to prioritise launching medical devices in markets outside the EU, potentially resulting in delayed market access for European patients.	

1) EMA (2024), Highlights- 10th Industry Standing Group (ISG) meeting, see link.

Companies' perspectives on the Artificial Intelligence Act

> While the objectives of the AI Act are commendable, there is concern that its stringent requirements may create unintended barriers for innovation within the EU. This could potentially give a competitive advantage to companies operating in less regulated jurisdictions.

> There is a risk of duplication in compliance efforts, particularly when AI functionalities are integrated into MDR-regulated devices. This could result in significant additional documentation and validation requirements, potentially impacting development timelines.

> Many companies are currently facing capacity and capability challenges related to the AI Act, including the need for more qualified personnel, supporting documentation, and compliance frameworks. These constraints may temporarily affect the pace of innovation.

Source: Copenhagen Economics based on interview with a pharmaceutical company.

Deliberate release of GMO & Contained use of GMM (1/3)

Directive 2001/18/EC & Directive 2009/41/EC

Description

Problem

Directive 2001/18/EC (Deliberate release):
Unregulated releases of genetically modified organisms (GMOs) may reproduce in the environment and cross national frontiers, thereby affecting other Member States. The effects on the environment may be irreversible, and the protection of human health and the environment requires a regulated release.[1]

Directive 2009/41/EC (Contained use):
Release of genetically modified micro-organisms (GMMs) in the course of their *contained use* may reproduce and spread, cross national frontiers, and thereby affect health and the environment in other Member States.[2]

- The GMO legislation causes delays in the development of novel medicines in the EU. This was confirmed by the EU's actions to tackle the COVID-19 pandemic, where medicinal products to prevent or reduce severity of COVID-19 were temporarily exempt from complying with some provisions of the GMO legislation to accelerate development and access to COVID-19 treatments or vaccines.[3]
- Most ATMPs do not survive long once they are outside of the human body, thereby minimizing the risk associated with the release of GMOs.[4]

Objective

Directive 2001/18/EC (Deliberate release):
The directive has two primary objectives[1]:
1. To protect human health and the environment when GMOs are deliberately released into the environment for any purpose or placed on the market.
2. To approximate laws and regulations across Member States, facilitating the functioning of the EU's single market for GMO products.[4]

Directive 2009/41/EC (Contained use):
The directive has three main objectives[2]:
1. To lay down common measures for the contained use of GMMs, with the aim of protecting human health and the environment.
2. To evaluate and reduce potential risks arising from operations involving the contained use of GMMs.
3. To set appropriate conditions of use through standardised procedures.

The GMO/GMM Directives applies broadly across sectors and industries, i.e. not just to the life sciences industry. Zooming in on medicinal products, the Directives applies where the genetic material has been altered in a way that does not occur naturally, including ATMPs, viral vector-based vaccines, and gene therapies. The revision of the General Pharmaceutical Legislation proposes that clinical trials with GMO-containing medicines are exempt from the Deliberate Release Directive's requirements, provided an Environmental Risk Assessment is submitted and assessed as part of the clinical trial application process.

1) EUR-Lex (2021), Directive 2001/18/EC, see link. / 2) EUR-Lex (2009), Directive 2009/41/EC, see link. / 3) EFPIA (2020), Call for more effective EU regulation of clinical trials with Advanced Therapy Medicinal Products consisting of or containing Genetically Modified Organisms, see link. / 4) Beattie et al. (2021), Call for more effective regulation of clinical trials with advanced therapy medicinal products consisting of or containing genetically modified organisms in the European Union, see link.

Deliberate release of GMO & Contained use of GMM (2/3)

Directive 2001/18/EC & Directive 2009/41/EC

Description

Objective (continued)

Directive 2001/18/EC (Deliberate release) provides for[1]:

- A prior authorisation system for the deliberate release of GMOs, including a case-by-case assessment of the risks to human health and the environment, i.e. a company must notify the competent authority and receive an authorisation before conducting a clinical trial with deliberate release of GMOs.
- Differentiated rules for the experimental release of GMOs at the national level and the placing on the market of GMOs at the EU level.
- Requirements concerning the labelling and monitoring of released GMOs.
- An opt-out system for Member States that refuse the cultivation of GMOs in their territory.

Directive 2009/41/EC (Contained use) provides for[2]:

- A risk assessment framework classifying contained use activities into four risk categories (class 1 to class 4), with differentiated procedures based on the level of risk.
- Emergency planning and accident notification requirements.
- Inspection and control measures by authorities.
- Information exchange between Member States regarding accidents.

- EC SME test: No, not required for Directives

- EC Competitiveness check: No, not required for Directives

Overall competitiveness assessment

The GMO/GMM Directives play a vital role in safeguarding human health and the environment. However, they have resulted in a fragmented and, in some parts, outdated regulatory framework that is ill-suited to the needs of the pharmaceutical sector. Advanced Therapy Medicinal Products (ATMPs) are currently subject to these Directives, which are widely regarded as an obstacle to their development primarily due to differences in national interpretation and requirements. The lack of flexibility in the existing regime poses a significant risk to innovation and may erode the EU's competitiveness in this critical field.

1) EUR-Lex (2021), Directive 2001/18/EC, see link. / 2) EUR-Lex (2009), Directive 2009/41/EC, see link.

Deliberate release of GMO & Contained use of GMM (3/3)

Competitiveness assessment	**Capacity to innovate**	The GMO/GMM Directives were drafted primarily with plant GMOs in mind with a goal to protect food consumers and crops from contamination. The Directives hamper capacity to innovate in the life sciences sector, as their requirements are not designed for medicinal products and have been implemented differently across Member States. This directly drives delays in the initiation of clinical trials, see the case study on the next page.[1] **(-)** As these are Directives, their provisions have been transposed into the Member States' national laws in 27 different ways, creating a fragmented and complex regulatory system with sometimes conflicting and lengthy timelines.[2] This leads to duplicative efforts for trial sponsors and contradictory feedback which is problematic in multi-country trial settings. **(-)** Having been developed for agricultural products, the requirements of the Directives, e.g. for documenting environmental impacts, are disproportionate as they do not reflect the controlled conditions of clinical and hospital use of medicinal products. This creates an unnecessary administrative burden and delays driven by regulatory review times. For example, the additional requirement for sponsors to make a GMO application may delay the start of a clinical trial by up to 12 months.[2] **(-)** The Directives add a regulatory layer on top of pharmaceutical regulation such as the Clinical Trials Regulation, thereby increasing the regulatory burden. **(-)** The national GMO competent authorities nearly always differ from the national health authorities involved with assessment of clinical trials.[3] Therefore, they do not necessarily review having clinical studies in hospital environments in mind.
	Cost of compliance	**(-)** As the Directives impose regulatory and documentation requirements, compliance costs have increased for all companies active in the European market. **(-)** The documentation requirements vary highly across Member States with some states requiring additional supporting documents as part of the GMO dossier. Furthermore, countries like France and Spain require the protocol synopsis in the local language.[4]
	International competiti-veness	International competitiveness has deteriorated because GMO requirements are stricter and more burdensome in the EU than in the US, giving US based developments a more flexible regulatory environment. **(-)** In the EU (and Japan), GMO risk assessment requirements must be met before initiating clinical trials, whereas in the US, a GMO risk assessment is generally not required before clinical trials. [4] Hence, the timeline for conducting clinical trials is slower in the EU compared to the US, making the EU a less attractive place for investments and clinical trials. Companies report to have chosen not to develop in the EU, because of the additional regulatory burden imposed by the GMO requirements.[5]
Market access		Based on company interviews, see the next page, we find that the fragmented system across Member States delays manufacturing authorisations and initiation of clinical trials, all of which ultimately delays market access of pharmaceutical products. This was noted in a communication from the European Commission to the European Parliament in the strategy for COVID-19 vaccines: "*There is considerable variety across Member States in the national requirements and procedures implementing the GMO Directives used to assess environmental risks of clinical trials of medicinal products that contain or consist of GMOs. This is likely to cause significant delay, particularly for multi-centre clinical trials in several Member States*."[6]

1) EFPIA (2020), Call for more effective EU regulation of clinical trials with Advanced Therapy Medicinal Products consisting of or containing Genetically Modified Organisms, see link. / 2) ARM, ebe, EFPIA, and EuropaBio (2017), Possible solutions to improve the European regulatory procedures for clinical trials with Advanced Therapy Medicinal Products consisting of or containing Genetically Modified Organisms, see link. / 3) Beattie et al. (2024), Clinical trial applications for investigational medicinal products that contain or consist of genetically modified organisms: industry experiences under the European Union Clinical Trial Regulation (536/2014), *Cell & Gene Therapy Insights 2024;10(6),375-395,* see link. / 4) Tajima et al. (2022), Impact of genetically modified organism requirements on gene therapy development in the EU, Japan, and the US, see link. / 5) Beattie et al. (2021), Call for more effective regulation of clinical trials with advanced therapy medicinal products consisting of or containing genetically modified organisms in the European Union, see link. / 6) European Commission (2020), EU Strategy for COVID-19 vaccines, see link.

Companies' perspectives on the GMO framework

Case study

The GMO directives were originally drafted for agricultural GMOs and not specifically intended for human medicines. This makes the regulation not fit for purpose, imposing highly burdensome requirements on medicines that ultimately delay development activities. As a developer of medicinal products, you need to have two pillars covered when bringing a product to the market: the manufacturing license and the marketing authorisation. However, with medicinal products containing or consisting of genetically modified organisms (GMOs), you add a third pillar, which introduces additional hurdles and causes complexity.

The classification of, e.g. an ATMP, as a genetically modified organism under EU law subjects them to additional, complex layers of regulation beyond what is mandated in the EU Pharmaceutical and Clinical Trials regulations.

First, when initiating trials with such an ATMP, GMO-specific authorisations must be obtained in each EU Member State where the trial is planned. GMO derived topics are part of the environmental risk assessments (ERAs) focused on preventing contamination. In the context of a treatment that is individually administered in a hospital context and under highly controlled conditions, these concerns are irrelevant, yet the administrative burden remains substantial and in some Member States the ERA process can take several months.

Second, since the legislation is a Directive, each EU Member State interprets the requirements differently, leading to duplicate efforts by the sponsor and contradictory feedback.

Even in simple handling of the medicinal product it is not obvious if an additional GMO authorisation is required. E.g. if the boxed product is sent from the manufacturing site to the spot of the administration in the hospital there is a different understanding of whether this is a "placing on the market" or a "deliberate release" or if this is still part of the manufacturing and therefore "contained use".

Third, while other countries have a one-stop-shop authority dealing with this topic, in Europe, developers need to interact with multiple authorities during research, development, clinical trials and marketing application such as the EMA and Commission, national authorities, environmental protection agencies and ethics committees, which makes the process much more complex and time-consuming.

These issues can lead to significant delays in the initiation of clinical trials solely due to varying and lengthy GMO authorisation procedures, hindering the timely development and testing of innovative therapies.

We need a risk-based approach in the biotech area. The GMO legislation needs to be modernized to reflect the unique nature of ATMPs and other innovative therapy approaches and to facilitate innovation and competitiveness in the biotech sector. Therefore, pharmaceutical companies would appreciate a full exemption of ATMPs of the GMO framework under the Pharmaceutical Legislation.

Source: Copenhagen Economics based on interview with a pharmaceutical company.

European Health Data Space Regulation (1/3)

Regulation (EU) 2025/327[1]

Description

Problem

The European Health Data Space (EHDS) aims to address major barriers that limit the effective use, access, and sharing of health data across the EU, including:[2]

- Fragmented systems: Health data infrastructure varies widely between Member States, creating interoperability challenges and limiting cross-border healthcare.
- For rare diseases, the problem with fragmented data across Member States exacerbates the already existing problem of limited data.
- Lack of citizen control: Individuals often struggle to access and manage their health data, especially when moving across borders.
- Barriers to secondary use: Inconsistent rules across countries hinder the reuse of health data for research, innovation, and public health policy.
- Market fragmentation: The lack of harmonised standards and certification restricts the growth of digital health solutions across the EU.

- As of early 2025, 11 Member States are connected to MyHealth@EU, with additional countries expected to join later this year.

Objective

The EHDS Regulation has the following main objectives[1]:

- Strengthen citizens' control over their own personal health data and enable cross-border healthcare with data portability.
- Ensure a consistent and efficient framework for the reuse of individuals' health data for research, innovation, policy-making and regulatory activities.
- Ensure interoperability and cybersecurity.
- Establishing a single market for electronic health record systems.

Key provisions include:

- **Individual data rights:** Citizens gain rights to access, manage, correct, and control sharing of their electronic health data across EU systems. They will be notified when data is used (both primary and secondary), and if any health threats are discovered.
- **Cross-border healthcare access:** Healthcare professionals can access patient records across Member States, supporting safe, informed, and continuous care.
- **Secondary use of health data:** Health data may be re-used for research, innovation, regulation, and policy under strict governance and data protection rules.
- **Interoperability and standards:** All electronic health record (EHR) systems must comply with the specifications of the European electronic health record exchange format, ensuring security and interoperability.
- **Governance and oversight:** Member States must establish national access bodies, while EU-level coordination ensures consistent implementation and secure infrastructure.

- EC SME test: No
- EC Competitiveness check: No

Overall competitiveness assessment

The EHDS Regulation is designed to be a fundamental game changer in the digital transformation of healthcare in the EU.[3] By enabling broader access to health data, it has the potential to significantly enhance health technology innovation across the EU. However, realising this potential depends on consistent implementation across Member States and protection of intellectual property. If managed effectively, the Regulation could strengthen the EU's position in global digital health and life sciences, supporting both innovation and long-term competitiveness.

1) EUR-Lex (2025), Regulation (EU) 2025/327, see link. / 2) European Commission (2022), Impact Assessment of the EHDS, SWD(2022)131 final, see link. / 3) European Commission (2022), European Health Union: A European Health Data Space for people and science, Press Release. see link.

European Health Data Space Regulation (2/3)

Competitiveness assessment		
	Capacity to innovate	The EHDS Regulation has the potential to increase the capacity for health technology innovation, provided that implementation is harmonised. However, uncertainties around intellectual property (IP) pose a significant risk to the success of the regulation. If not clearly and consistently addressed, they could discourage data sharing altogether, undermining the positive impacts on capacity to innovation – and the regulation as a whole: **(-)** Uncertain IP protections could constrain data sharing. Despite safeguards, the application of IP protection rules by national Health Data Access Bodies (HDABs) remains unclear, posing a risk to proprietary health data. **(+)** Easier access to high-quality, harmonised datasets across the EU enables broader and faster research and development of new therapies. For example, the Solve-RD project managed to diagnose 500 new genetic cases for patients across the EU by leveraging the European Reference Networks to harmonise and share data.[1] This also emphasizes the EHDS's potential to address data issues for rare diseases by providing a unified access point for rare disease data, thereby supporting more effective and collaborative research. **(+)** Lower barriers to data access for small and mid-sized technology developers help level the playing field and broaden participation in health data-driven innovation and contribute to their competitiveness.[2] **(+)** A federated data infrastructure reduces fragmentation across Member States, enhances interoperability, and improves data usability and analytical capacity - particularly important in areas such as rare diseases. **(+)** Aligning with EHDS standards incentivises streamlining of internal data systems, unlocking the value of proprietary data and increasing readiness for collaborative innovation. **(-)** Without strong coordination, Member States may interpret data access, technical standards, or opt-out mechanisms differently, thereby undermining interoperability and reducing the effective capacity gains that are key objectives of the Regulation. **(-)** Variability in opt-out implementation across Member States could reduce the availability and representativeness of health data, weaken the statistical power of research and increase bias.
	Cost of compliance	The broad definitions of health data may increase the cost of compliance as companies will want to mitigate legal and reputational risks by over-complying with the Regulation: **(-)** Broad and imprecise definitions such as those for "*health data holder*" and "*electronic health data*" create uncertainty around regulatory obligations. This lack of clarity may lead health technology developers to adopt over-compliance strategies to mitigate legal and reputational risk and potential fines. As a result, firms may face increased compliance costs.[3] For small and mid-sized companies, these costs may be disproportionately high, diverting resources from innovation to compliance. **(-)** Interactions with HDAB, including the obligation to report metadata catalogues (with accompanying descriptions), will increase compliance costs and increase the risk of sharing proprietary data.

1) Eurordis (2023), Solve-RD, see link. / 2) European Commission (2022), Executive summary of the impact assessment report, see link. / 3) These costs include expanded legal review to determine applicability, sharing of data containing trade secrets, broadly defined categories of data in scope and rules for international transfer of data, conservative internal data-sharing policies, re-tooling of systems to meet uncertain or evolving obligations, additional risk mitigation measures, such as withholding data or engaging external counsel.

European Health Data Space Regulation (3/3)

Competitiveness assessment

International competitiveness

The EHDS Regulation can increase the attractiveness of the EU market for health technology investments:
(+) A well-implemented EHDS could position the EU as a frontrunner in therapeutic discovery and evidence-based regulatory science. This can attract global health technology R&D investments by offering a favourable ecosystem for data-rich product development and approval. The EHDS is expected to support a 20-30 per cent growth in the digital health market.[1]
(+) By operationalising the use of real-world evidence (RWE) at scale, the EU gains a first mover advantage in shaping global norms on how digital health data informs regulatory and HTA decisions - turning a compliance obligation into a strategic export.
(-) The EHDS Regulation's complex privacy and consent mechanisms may create implementation challenges that could disadvantage European pharmaceutical companies compared to counterparts operating in less regulated environments

Market access

(+) The EHDS can improve market access by providing higher-quality real-world data for regulatory and HTA decisions. Access to standardised, cross-border health data supports real-world evidence (RWE) generation, enhancing safety monitoring and patient-centered research. This strengthens the case for faster, more informed approvals and reimbursement decisions, helping new therapies reach patients more quickly ***if*** EU HTA recognises RWE as valid clinical evidence.

1) EHDS (2025), EHDS Overview, see link.

Companies' perspectives on the European Health Data Space Regulation

> The EHDS has the potential to significantly improve access to health data - a key constraint for many life sciences stakeholders. However, the impact will largely depend on the fairness and clarity of its implementation.

> It is important to balance equitable access to publicly funded data with appropriate incentives for private data holders. A key concern is that mandatory data sharing could unintentionally compromise the competitive positioning of EU-based innovators, especially if global access is not reciprocated.

Source: Copenhagen Economics based on interview with a pharmaceutical company.

Proposed legislations

EU General Pharmaceutical Legislation

Description

Problem

The General Pharmaceutical Legislation is being revised to address the following key shortcomings of the current legislation[1]:

- Patient's medical needs are not sufficiently met.
- Affordability of medicinal products is a challenge for health systems.
- Patients have unequal access to medicinal products across the EU.
- Shortages of medicinal products are an increasing problem in the EU.
- The medicinal product life cycle can have negative impacts on the environment.
- The regulatory system does not sufficiently cater for innovation and in some instances creates unnecessary administrative burdens.
- The EU has longer regulatory approval timelines (in 2022), averaging around 430 days, compared to 322 days in Japan, 334 days in the US, 347 days in Australia, 351 days in Canada, and 418 days in Switzerland.[2]
- Unmet medical needs remain significant – 95 per cent of rare diseases do not have an authorised treatment.[3]
- On average, it takes 578 days for a new medicine to become available in European markets.[4]

Objective

The revision aims to balance the needs of patients, healthcare systems, and the pharmaceutical industry through the following main objectives[5]:

- Ensure timely and equitable access to safe, effective, and affordable medicines for all patients across the EU.
- Strengthen the security of supply and ensure that medicines are available to patients, regardless of where they live in the EU.
- Foster an attractive and innovation-friendly environment for research, development, and production of medicines in the EU.
- Promote environmental sustainability in the development and use of medicines.
- Tackle antimicrobial resistance (AMR) and reduce the environmental impact of pharmaceuticals through a "One Health" approach.

To achieve the objectives, the following provisions are proposed (non-exhaustive list), see next two pages for a deep dive into the comparison of Commission, Parliament and Council positions:

- **Updating the incentives for innovation and market access:**
  - **Modulating RDP and market protection (MP) frameworks** by reducing the baseline RDP period in the Commission and Parliament positions, and by reducing the baseline MP period in the Council position.
  - **Modulating the length of market exclusivity** for orphan medicinal products in the Commission and Parliament positions.
  - Offering regulatory incentives for medicines that address **(high) unmet medical needs or are launched in all EU Member States** in the Commission proposal**.**
- **Streamlining the regulatory processes**[1]:
  - Simplifying **approval procedures** and **reducing the assessment time** for medicines from 210 to 180 days. However, the Council position does not propose any changes to assessment times.
  - Granting marketing authorisations (MAs) for an unlimited time as a general rule and introducing simplified procedures for generic medicines.
  - Introducing **regulatory sandboxes** for novel treatments under certain conditions.
- **Enhancing security of supply**:
  - Strengthening obligations for companies to report and prevent shortages of medicines.
  - Enhancing EMA's role in monitoring and coordinating shortage responses.
- **Enhancing environmental protection**:
  - Implementing **stricter environmental risk assessments requirements** as part of the marketing authorisation process.
  - **Exempting GMO-containing medicines** from the Deliberate Release Directive, provided an environmental risk assessment is submitted and assessed as part of the clinical trials application.

1) EUR-Lex (2023), COM/2023/193 final, see link. / 2 European Commission (2024), The future of European competitiveness. Part B, p. 193, see link. / 3) European Parliament (2024), Tackling rare diseases, see link. / 4) EFPIA (2025), EFPIA Patients W.A.I.T. Indicator 2024 Survey, see link. / 5) European Commission (2023), Reform of the EU pharmaceutical legislation, see link.

Overview of the EU General Pharmaceutical Legislation proposals (1/2)

Simplified comparison of the three positions

Topic	Commission	Parliament	Council
Regulatory Data Protection (RDP)	• Six-year baseline RDP, extendable with the following conditions: +2 years if EU market launch and supply; +6 months if addressing unmet medical need; + 6 months if comparative clinical trials; + 1 year if significant benefit • Two-year market protection (MP) • Cap (RDP+MP): 12 years	• 7.5-year baseline RDP, extendable with the following conditions: +1 year if addressing unmet medical need; + 6 months if comparative clinical trials; +6 months if EU R&D collaboration • Two-year market protection (MP), can be extended by +1 year if significant benefit • Cap: 11.5 years (hereof max 8.5 years RDP)	• Eight-year RDP baseline • One-year market protection, can be extended by +1 year if addressing unmet medical need; +1 year if three cumulative conditions are met (comparative clinical trials + conducting clinical trials in several Member States + MAA first in EU or within 90 days from other jurisdiction) • Cap: 11 years (8 years RDP + 3 years MP)
Orphan Exclusivity Modulation (OME)	• Nine-year OME baseline • 10 years for high unmet medical need (HUMN) – extendable by +2 years with Global Orphan Marketing Authorisation (GOMA, see below) and +1 year if launch in all Member States	• Nine-year OME baseline • 11 years for HUMN – extendable by +2 years with GOMA	• 10-year OME for all products • Concept of HUMN is removed • OME extendable by +2 years with GOMA
Global Orphan Marketing Authorisation	• Measure to prolong market exclusivity if the MA holder obtains a MA for new therapeutic indication for a different orphan condition if two years before end of OME • One-year extension – twice maximum	• No change compared to Commission proposal	• No change compared to Commission proposal
Launch conditionality /access	• The condition to launch in all Member States is linked to the RDP incentives.	• The Parliament proposal de-links the launch conditionality from RDP incentives. • However, the proposal introduces an access proposal in which companies must file for pricing and reimbursement and subsequently in Member States that request it.	• Companies are required to place the product on the market and supply upon Member State request (within 4 years). • If the company does not comply, they risk losing market protection.

Overview of the EU General Pharmaceutical Legislation proposals (2/2)

Simplified comparison of the three positions

Topic	Commission	Parliament	Council
Regulatory reform	• 180 days for MA approval (reduced from 210 days) • EMA is restructured with 2 main committees and working parties (that support main scientific committees)	• 180 days for MA approval (reduced from 210 days) • Keeps new EMA structure as in the Commission proposal but introduces four ad hoc working groups – ATMPs, OMP, PAED, ERA	• 210 days for MA approval (as is) • No changes to EMA structure • Working parties can be established to provide expertise to CHMP
Decentralised manufacturing	• Decentralised sites carrying out manufacturing or testing steps under a qualified person do not require separate manufacturing authorisation (MA). • Must be justified by the quality, safety, efficacy or patient benefit • Can be withdrawn if the use case cannot be justified	• Decentralised sites carrying out manufacturing or testing steps under a qualified person do not require separate manufacturing authorisation (MA).	• Decentralised sites carrying out manufacturing or testing steps under a qualified person do not require separate manufacturing authorisation (MA). • Article 26a specifies in detail which products and how the decentralised manufacturing approval applies.
Medicine shortages and supply chains	• Introduction of various requirements, e.g., shortage prevention and mitigation plans, notifications of disruption	• No major changes • More stringent requirements on MA holder	• Shortage prevention plan only for critical medicines and critical shortages (unlike the Commission and Parliament positions where they were applied more broadly) • Member States can request to expand the plans
Environmental Risk Assessment (ERA)	• MA can be refused or revoked in case of insufficient ERA • ERA requested for products approved before 2005	• More difficult to refuse/revoke ERA including for products approved before 2005 • ERA should cover full lifecycle	• MA can be refused only if ERA is incomplete without justification and not possible to complement with post-MA mitigation measures • For products before 2005, MA can be revoked if ERA is incomplete or identified as a potential harm

EU General Pharmaceutical Legislation (1/3)

Description

Objective (continued)

- **Creating AMR initiatives**:
  - Introducing **transferable data exclusivity vouchers** for antimicrobials that address AMR.
  - Promoting responsible use of antimicrobials through dedicated regulatory measures.
- **Setting up support for SMEs and non-profit developers**:
  - Enhancing early regulatory and scientific support from the EMA.
  - Allowing non-profit entities to submit evidence for new therapeutic indications.
- **Measures related to quality and manufacturing (in the Directive proposal):**
  - In the Commission proposal, the marketing authorisation may apply for **decentralised manufacturing sites** and not only centralised sites.

- EC SME test: No
- EC Competitiveness check: No

Overall competitiveness assessment

The revision of the General Pharmaceutical Legislation holds significant potential to ensure timely and equitable access to medicines, boost innovation, and make the EU pharmaceutical industry competitive. However, initiatives aimed at adjusting innovation incentives (including a baseline reduction of RDP) and the increased administrative requirements (e.g., related to shortages or to ERA) may make the EU a less attractive market for the pharmaceutical industry, potentially leading to reduced innovation and a decline in the EU's life science competitiveness.

Competitiveness assessment

Capacity to innovate

The proposal puts forward multiple measures that will increase capacity to innovate through enhanced regulatory efficiency. However, modulation of incentives including a baseline reduction of RDP or MP will likely dampen investment incentives and may risk undermining the overall objectives of the revision. Therefore, we assess the net impact of the proposal on capacity to innovate as negative.

(-) Modulation of incentives: The Commission proposal reduces the baseline RDP period, and a shorter protection period will negatively affect incentives to innovate, as innovations are protected from generics for a shorter period which can have a negative impact on future revenue streams.[1] Effective lower protection dampens investment incentives and leads to a reduction in R&D investments: empirical research has shown that a one-year reduction in the mean effective protection period is associated with 11.89% lower pharmaceutical R&D investments in the long run.[2] A further study has quantified the long-term annual R&D loss of a one-year reduction of RDP in the EU at EUR 1.64bn[1], and the Commission proposal would lead to a decrease in EU innovation of 22%.[3] This is higher than the European Commission's calculation of cost-savings generated in healthcare systems through earlier entry of generics. Criteria for modulation, i.e. the conditional granting of extra years of RDP based on criteria such as an UMN definition, comparative clinical trials, and showing significant benefit, are insufficiently predictable to count towards an incentive in the current system as investors will base their valuations on baseline protections (RDP and OME).[4] Against this background, the return to 10 years of baseline OME without conditions by the Council is positive, but does not constitute an *improvement* of capacity to innovate.

(+)/(-) Regulatory efficiency: The Commission proposal to reduce assessment times for medicines from 210 to 180 days had the potential to increase regulatory efficiency and positively impact capacity to innovate. However, investors expressed concern that the EMA would not be able to meet the new deadlines due to lack of resources, and the provision would only have a positive impact if the EMA is provided with more resources.[4] The Council position suggests to keep the assessment time at 210 days, thereby eliminating the positive effect for increased regulatory efficient if adopted.[5]

1) Copenhagen Economics (2024), Cost and value of regulatory data protection, see link. / 2) Copenhagen Economics (2018), Study on the economic impact of supplementary protection certificates, pharmaceutical incentives and rewards in Europe, p. 101, see link. / 3) Dolon (2023), Revision of the General Pharmaceutical Legislation: Impact Assessment of European Commission and EFPIA proposal, see link. / 4) FTI Consulting for EUCOPE (2024), The Economic Lens: Understanding what makes the EU attractive for life science investments, see link. / 5) Council of the European Union (205), 2023/0131(COD) p. 14, see link.

EU General Pharmaceutical Legislation (2/3)

Competitiveness assessment

Capacity to innovate (continued)

(+) Scientific support: The proposal strengthens EMA scientific support for medicine developers before submission of MA applications, especially for SMEs, and enhances early regulatory and scientific support for developers of promising medicines. This has the potential to reduce the burden of developing innovative treatments and positively affect the capacity to innovate and attract investors.[1] However, it is important to note that the definition of SMEs is narrower than the term small and mid-sized companies, that we utilise throughout this report. Hence, many small and mid-sized companies may not benefit from the scientific support.

(+) Regulatory sandboxes: The proposal introduces regulatory sandboxes for new treatments, allowing more flexibility in the development. Such sandboxes benefit regulators by enabling learning, experimentation, and improved policy-making while enhancing engagement with innovators. Regulatory sandboxes enable companies to access markets faster, and they reduce uncertainty by setting clearer regulatory expectations - especially helpful for SMEs and start-ups.[2,3] Companies report that regulatory sandboxes are very important for future innovation, see the companies' perspectives on p. 46.

(+) Decentralised manufacturing: The Commission proposal for a revision of the EU Pharmaceutical Directive (Articles 142-153) establishes a regulatory framework for decentralised manufacturing. Companies report that the possibility of not requiring authorisation and/or accreditation of decentralised manufacturing sites affects their work positively as they no longer would need authorisation for each decentralised site but rather one single authorisation for the control site, see companies' perspectives on p. 46. This particularly holds for ATMPs. The proposal extends this concept to other medicines as well. A single authorisation for decentralised manufacturing will improve the regulatory efficiency and allow more resources to be spent on R&D. However, the Council position adds more fixed requirements for decentralised manufacturing, removing some flexibility and hampering the positive effect.[3]

(+) Transferable data exclusivity vouchers: The vouchers will likely incentivise R&D and innovation in priority antibiotics and antimicrobials, an area where investment has previously been relatively low due to low commercial returns. The transferable nature of the voucher makes it highly incentivising for companies, as they can use it for another medicine of their choice or sell/license it to another company.[4] However, the introduction of budget caps or other restrictions on the vouchers could limit their effectiveness in stimulating innovation.

(+) GMO framework: Adopting a risk-benefit approach to providing a derogation from the requirements in the GMO framework will increase innovation as the regulation becomes more efficient.[5]

1) FTI Consulting for EUCOPE (2024), The Economic Lens: Understanding what makes the EU attractive for life science investments, see link. / 2) OECD (2023), Regulatory sandboxes in artificial intelligence, see link. / 3) Cornelli et al. (2023), Regulatory sandboxes and fintech funding: evidence from the UK, *BIS Working Papers No 901*, see link. / 4) For example, in 2012 Janssen was awarded a tropical disease voucher Sirturo, a treatment for multi-drug-resistant tuberculosis which they used to expedite the regulatory process for Tremfya (guselkumab) to treat plaque psoriasis. / 5) ARM, EFPIA, EuropaBio, and Beattie (2021), Call for More Effective Regulation of Clinical Trials With Advanced Therapy Medicinal Products Consisting of or Containing Genetically Modified Organisms in the European Union, *Human Gene Therapy Vol. 32, No. 19-12*, see link.

EU General Pharmaceutical Legislation (3/3)

Competitiveness assessment

Cost of compliance

The effect on cost of compliance is primarily negative, as the proposal introduces measures that increase the regulatory burden and are unclear on how the simplification measures will be implemented.
(+)/(-) On the one hand, the revision aims to reduce the administrative burden by simplifying regulatory procedures and shortening authorisation timelines. However, if and how the simplification will be implemented is uncertain. As highlighted by the Regulatory Scrutiny Board based on the Commission proposal, the proposal is not clear on how this will be achieved, and they do not find any costs or savings related to streamlining.[1]
(-) On the other hand, new requirements like environmental risk assessments, shortage measures (e.g., shortage prevention plans or notifications of supply disruptions), and stricter data protection rules may increase compliance costs for pharmaceutical companies.

International competitiveness

As for the capacity to innovate, the modulation of incentives may make the EU a less attractive market for the pharmaceutical industry. At the same time, streamlined regulatory processes and enhanced scientific support for SMEs can give these companies an advantage compared to companies based in other regions. However, all things equal, the potential negative effects of a baseline reduction of RDP and/or MP and other obligations e.g. related to access or administrative compliance such as ERA and shortages will affect the attractiveness of the EU market to such an extent that we estimate that the net effect on international competitiveness is negative.
(+) Streamlined regulatory processes and enhanced scientific support for small- and medium-sized companies could, all things equal, give EU based smaller companies a comparative advantage compared to those located in other regions.
(-) Reduced baseline RDP risks making the EU a less attractive market for R&D investment as innovations are protected for a shorter period of time.[2]
(-) Companies report that the EU is lagging behind the US and Japan in its ability to conduct regulatory work. For example, even after EMA approval, medicine developers face significant challenges navigating the fragmented reimbursement processes across EU countries, often delayed by protracted negotiations, budget constraints, and varying national requirements.[3] The administrative system in the EU is not large and well-functioning enough to ensure smooth and fast-paced regulatory work – and this is to some degree driven by the decentralised processes in the EU, see companies' perspective on p. 46.

Market access

The General Pharmaceutical Legislation's impact on market access is likely to be negative. The lack of effective measures within the legislation to address delayed market access can be seen as a missed opportunity.
(-) The Council's return of **regulatory approval timelines** to 210 days from the initially proposed reduction to 180 days would constitute a missed opportunity for speeding up time to market.
(-) Potential **market access delays** due to stricter environmental risk assessment requirements.
(-) The European Commission's conditional two-year extension of RDP for companies that launch in all 27 Member States within two years of approval was unrealistic for small- and mid-sized companies to achieve and did not address the many factors that drive access delays and that are in part rooted in national P&R systems. However, since this part of the proposal was reshaped by the European Parliament and the Council of the European Union, we do not include it in our weighting.

1) Regulatory Scrutiny Board Opinion (2022), Revision of the general pharmaceutical legislation, see link. / 2) Copenhagen Economics (2024), Cost and value of regulatory data protection, see link, and Copenhagen Economics (2023), Regulatory Data Protection for pharmaceuticals, see link. / 3) IQVIA (2024), Assessing Availability of New Drugs in Europe, Japan, and the U.S., see link.

Companies' perspectives on the EU Pharmaceutical Legislation

> The data exclusivity question is crucial. It depends on the company portfolio, with some companies relying more on patents and others on regulatory data protection. (…) shorter protection periods may impact decisions on where to invest for clinical trials or where to file the product.

> There are some very important elements that facilitate decentralised manufacturing in the Commission proposal, and these are very important for "non-standard" medicines. Today, each manufacturing site (central or decentralised) requires an accreditation. Allowing decentralised sites to rely on the manufacturing authorisation of the central site would reduce the administrative burden of requiring (national) accreditation for each single decentralised site and would improve technology transfer and patient access to ATMPs.

> There was a missed opportunity to do something more ambitious with the GPL. The regulatory provisions could have been more ambitious, similar to programs in the US like the breakthrough designation. The main question in Europe is the capacity of the regulatory network to get the work done, which is decentralized and spread out compared to the FDA or PMDA in Japan.

> The positive impact of new measures such as the regulatory sandbox or shortened review periods are very small compared to the negative impact of shortened RDP.

> For ATMPs it is difficult to test innovative manufacturing processes due to current legislations including the GMO framework. To this end, the regulatory sandbox is very important. While the point of care (i.e. the location of where the medicine is administered) is not yet included in the revision of the pharmaceutical legislation, the regulatory sandbox could provide a controlled environment to explore the medicine in an actual but controlled environment and also further develop the regulatory framework in an innovative manner.

> The European market is not as attractive for launching products quickly compared to the US, Japan, and China. This is because Europe is lagging behind in terms of ambition for innovation and willingness to accept innovation from a regulatory perspective.

Source: Copenhagen Economics based on interview with pharmaceutical companies.

Critical Medicines Act (1/2)

Description

Problem

The EU's medicinal supply is dependent on external suppliers for pharmaceutical products and ingredients, making the supply of especially generic medicines and the access to medicines vulnerable in times of geopolitical tensions and pandemics, ultimately threatening public health.

- In 2020, 60-80 per cent of active pharmaceutical ingredients (APIs) for generic medicinal products used in the EU were manufactured in India or China.[1]
- 90 per cent of the APIs on the Critical Medicines list are generics.[1]
- Over the past 10 years, there has been an increase in the number of shortages in the EU from a few in 2008 to nearly 14,000 in 2019.[2] These shortages and the underlying supply-chain vulnerabilities mostly concern generic medicines but may also affect innovative medicines.[3,4] For instance, the Critical Medicines Alliance identifies that current price-focused procurement has led to the offshoring of generic medicine production (60-80 per cent of APIs to Asia), creating supply vulnerabilities.[3]

Objective

The general objective of the Critical Medicines Act (CMA) is to improve the availability, supply and production of critical medicines within the EU, thereby ensuring a high level of public health protection and supporting security of the Union. Additionally, the CMA also aims to increase access to other medicines of common interest, such as medicines for rare diseases, to address the fact that some medicines are not available in certain markets.[5] Finally, some aspects of the CMA apply to medicines of common interest facing market access issues in a few Member States.

Key provisions are[6]:

1. To facilitate investments in EU-located manufacturing capacities for critical medicines, their active substances and other key inputs in the EU e.g. through **Strategic Projects**, which can get **financial support through state aid or EU programmes** and should receive administrative and regulatory support, e.g. permit-granting processes, from Member States authority to drive swift roll-out. Companies will be obliged to prioritise EU supply, if they have benefitted from financial support for a Strategic Project.
2. To lower the risk of supply disruptions and strengthen availability by incentivising supply chain diversification and resilience in the **public procurement procedures** for critical medicines and other medicinal products of common interest through requiring Member States to **apply procurement criteria that prioritise security of supply over price alone** (the "Buy European" mechanism, MEAT criteria[7]). When imposing contingency stocks on supply chain actors, Member States shall ensure that these requirements are proportionate and respect the principles of transparency and solidarity;
3. To leverage the aggregate demand for critical medicines and other medicines of common interest amongst participating Member States through **collaborative procurement procedures**[8];
4. To broaden the supply chains of critical medicines and other medicinal products of common interest and reduce dependencies on single suppliers through **international partnerships**.

The above provisions apply to (1) Critical Medicines defined in the Union List of Critical Medicines, which include innovative and generic medicines and (2) medicines of common interest, which are only innovative medicines.

- EC SME test: No
- EC Competitiveness check: No

Given the urgent need to address the supply shortages, the regulation is proposed without an impact assessment.[5]

Overall competitiveness assessment

The Critical Medicines Act primarily targets the manufacturing and supply of critical medicines. While certain provisions, e.g. facilitation of building permits, might reduce some compliance costs, the Act will overall increase compliance costs. The lack of an impact assessment or understanding of actual use of collaborative procurement creates uncertainty.

1) Critical Medicines Alliance (2025), Strategic report of the Critical Medicines Alliance, see link. / 2) European Commission (2023) EU Pharmaceutical Legislation Impact Assessment, see link. / 3) Critical Medicines Alliance (2025), Strategic Report of the Critical Medicines Alliance, see link. / 4) European Commission (2022), Vulnerabilities of the global supply chains of medicines, see link. / 5) European Commission (2025), Critical medicines Act, see link. / 6) European Commission (2025), Proposal for a Critical Medicines Act, see link. / 7) Need to make use of **M**ost **E**conomically **A**dvantageous **T**ender (MEAT) criteria mandatory that take into account the supply security and availability considerations. / 8) Collaborative procurements may be: (1) Cross-border procurement of medicinal products of common interest by three or more Member States, with the Commission as facilitator; (2) Commission-led procurement for critical medicines or medicinal products of common interest (post-JCA) on behalf of at least nine Member States, with Member States retaining the final purchasing decision; (3) Fully Commission-coordinated joint procurement for the same medicines as in (2), initiated by the Commission for at least nine Member States.

Critical Medicines Act (2/2)

Competitiveness assessment	**Capacity to innovate**	The overall impact of the CMA on capacity to innovate is likely to be positive for critical medicines but negative for medicines of common interest: **(+)** Market-based incentives (Buy European mechanism, procurement criteria that go beyond price) and financial aid (state aid and EU funding) will imply that companies will, for critical medicines, only construct/move manufacturing capabilities into the EU or take other measures to enhance security of supply if the benefits of doing so outweigh the costs. This will however only happen if the incentives are also effectively implemented in practice. For instance, a Commission study found that the MEAT criteria are today applied inconsistently across EU member states in the public procurement of medicines, with price prevailing as the sole or dominant procurement criterion in most contracts.[1,2] **(-)** The lack of a thorough assessment of the impact of collaborative procurement in combination with a potential wide definition of medicines of common interest increases uncertainty, which may overall dampen investment incentives. Collaborative procurement on one hand may drive higher sales volumes for individual products across the EU, but on the other hand may drive down prices, with the overall revenue impact being uncertain.	Critical medicines Medicines of common interest
	Cost of compliance	As the CMA will reward a diversified EU supply chain, the documentation required to demonstrate this will-all things equal-increase compliance costs of pharmaceutical companies. **(-)** The adjustments of the public procurement procedures to strengthen the supply chain by e.g. including a broader set of requirements in the procurement process procedures, such as diversified sources of input material and monitoring of supply chains may increase the costs for the companies. The companies will need to demonstrate diversified supply chains to win the bid, and this will result in an increased administrative burden.[3] **(-)** Stockpiling obligations, requirements to report on stocks, and supply chain monitoring will increase costs.	
	International competiti-veness	The effects of the CMA on international competitiveness are unclear, specifically as the impact assessment is still to be published. The upcoming impact assessment can help clarify what the effect on international competitiveness may be, and which of the following factors will impact international competitiveness the most: **(+)** For strategic projects, European manufacturers could gain an international advantage given the EU (state aid) financial support.[4] European suppliers that can guarantee more resilient supply chains may, as a result of effective application of the MEAT criteria, win a larger share of tenders in the EU. **(+)** By reducing dependency on third countries, the proposal aims to create a more resilient and competitive domestic industry.[4] **(-)** Production of mature and generic medicines is approximately 20-40 per cent cheaper in Asia compared to the EU due to lower labour costs and less stringent regulatory requirements.[5] Having to use European production facilities to a significant extent, European manufacturers may struggle to compete globally even with additional support measures.	
Market access		The proposal has significant positive impacts on market access through increasing security of supply. **(+)** The CMA can improve the speed of market access by addressing shortages and ensuring a more reliable supply of critical medicines. **(-)** The effects of collaborative procurement (in all three forms as put forward in the proposal) have not been assessed in an impact assessment, and the effects on prices, volumes and therefore revenues are unclear. This coupled with the uncertainty as to what 'other medicinal products of common interest' are and hence which medicines can be subject to collaborative procurement creates uncertainties as to what the net effect on market access is. It is for instance, not clear, if collaborative procurement will be used only to address security of supply issue or as a tool to increase bargaining power to achieve lower prices.	

1) European Commission (2022), Study on Best Practices in the Public Procurement of Medicines, see link. / 2) European Commission (2022), Study on Best Practices in the Public Procurement of Medicines, Annex 4, see link.
3) Representation in Ireland (2025), Commission proposes Critical Medicines Act to bolster the supply of critical medicines in the EU, see link. / 4) European Commission (2025), Critical medicines Act, see link. / 5) Euractiv (2025), Why Europe wants to take back control of medicines' production, see link.

Companies' perspectives on the Critical Medicines Act

> The Critical Medicines Act (CMA) aims to ensure the availability of essential medicines in the EU. However, sustainability legislations such as the Urban Wastewater Treatment Directive (UWWD) risk undermining this objective. The investment required to comply with the UWWD can significantly erode profit margins, especially for generic medicines. This could result in negative profit margins, threatening the commercial viability of certain products.
>
> In many cases, governments have indicated that they are unwilling to increase reimbursement beyond the original price, potentially forcing manufacturers to withdraw certain medicines from the market. This, in turn, could lead to these medicines being added to the Critical Medicines List - not due to supply chain issues, but as a direct consequence of overlapping legislative requirements.
>
> In response, companies are urging Member States to conduct national impact analyses of the legislation in terms of security of supply before implementing it.

> The Critical Medicines Act poses some challenges - particularly regarding its joint procurement provisions. While the list of critical medicines per se is well-intended, the proposed mechanisms for joint or collaborative procurement raise concerns.

Source: Copenhagen Economics based on interview with a pharmaceutical company.

Patent Package (1/2)

Reform of the SPC regime[1] and a new EU-wide compulsory licensing instrument[2]

Description

Problem

The European Commission is harmonising the patent law within the EU due to the following two problems:[3]

Firstly, although the Unitary Patent system is now operational, the application and enforcement of **Supplementary Protection Certificates** (SPCs) - which extend patent protection for medicinal and plant products undergoing lengthy regulatory approval - remain governed and enforced at the national level. This fragmented approach creates legal uncertainty and administrative burden for companies seeking consistent IP protection across the EU.

Secondly, **compulsory licensing** (CL) is a last-resort remedy that enables access to patented technologies without the consent of the holder. The current CL regime across 27 Member States remains fragmented, resulting in legal uncertainty, limited territorial scope, and lack of alignment with EU-level crisis instruments. This hinders rapid, coordinated action across borders.

- Direct data on unitary SPCs does not exist, however, since 2023 2,055 unitary patents have been registered at the EPO in the pharmaceutical IPC class (A61K) opted for unitary patent protection. This suggests an interest in the system.[4]
- Compulsory licensing was not used during the COVID-19 pandemic to get access to vaccines.[5] This indicates that compulsory licensing might not be necessary from a European perspective.

Objective

The revised SPC framework aims to introduce a centralised procedure and a unitary SPC, to ensure consistent, efficient protection across the EU. It seeks to enhance legal certainty, support innovation, and align with the Unitary Patent system.

Compulsory licensing aims to create a predictable and workable system in the EU for crisis-response purposes.

The revision of the SPC Regulation provides for:

- The introduction of a unitary SPC to complement the Unitary Patent.
- The introduction of a centralised examination procedure, implemented by EUIPO, in close cooperation with national IP offices in EU Member States.

Key provisions of EU CL Regulation are as follows:

- The introduction of a unified compulsory licensing system applicable across all Member States to replace fragmented national regimes.
- Alignment of compulsory licensing with existing EU crisis instruments to support coordinated emergency responses.
- Procedure for granting compulsory licence and renumeration.
- Provisions for domestic use and export.

- EC SME test: SPC: Yes, CL: Yes
- EC Competitiveness check: SPC: No, CL: No

Overall competitiveness assessment

While the SPC reform may enhance investment conditions by lowering compliance costs and improving legal certainty, the proposed EU compulsory licensing regulation raises concerns. Stakeholders warn that it could narrow effective IP protection by creating uncertainty around when a licence can be issued. The lack of clear criteria - particularly for terms such as “crisis” and “emergency” - could undermine investor confidence and legal predictability.

SPC CL

1) EUR-Lex (2023), Proposals for regulations on supplementary protection certificates - COM(2023)221, COM(2023)222, COM(2023)223 and COM(2023)231, see link, link, link, and link. / 2) EUR-Lex (2023), Proposal for the regulation on compulsory licensing for crisis management - COM(2023)224, see link. / 3) European Commission (2023), Intellectual property: harmonised EU patent rules boost innovation, investment and competitiveness in the Single Market, see link. / 4) EPO (4 June 2025), Requests for unitary effect dashboard, see link. / 5) See for example from nature.com (2022), see link for this statement.

Patent Package (2/2)

Competitiveness assessment	Capacity to innovate	Patents are essential to fostering innovation in the health technology industry: by giving time-limited protection from generic/ biosimilar competition, patents allow companies to recoup the investment and be rewarded for the risk taken in developing the medicinal product.[1] Eroding (or reducing) the protection - by narrowing its scope, shortening the duration - diminishes the incentives to invest, ultimately weakening the sector's capacity to innovate. While the proposal for SPC reform aims to improve the efficiency of protection without undermining its scope, concerns have been raised in relation to the proposed EU CL. The SPC reform introduces improvements that may enhance investment conditions: **(+)** Simplification of administrative procedures and harmonisation of rules coming with unitary SPC and a centralised administration procedure has the potential to increase legal certainty in the EU. Greater legal certainty is expected to promote investments in risky projects.[2] In contrast, the EU CL proposal raises legal and investment concerns: **(-)** Stakeholders have raised concerns that the proposed EU compulsory licensing regulation lacks clear and objective criteria for determining when a "crisis" or "emergency" exists.[3] While these terms are referenced in other areas of EU law, their meaning in the context of intellectual property remains ambiguous and open to interpretation. This ambiguity could grant broad discretion to the Commission, introducing legal uncertainty and potentially deterring investment in the European market.[4] **(-)** Stakeholders have consistently called for stronger safeguards to ensure that compulsory licensing is used strictly as a measure of "last resort", i.e. only after all voluntary avenues have been exhausted. The Council's June 2024 position responds to some of these concerns.[5] It reinforces the requirement to explore alternative solutions before issuing a compulsory licence. It also enhances the role of an advisory body, including national IP experts, to support the Commission's assessment of whether the conditions for granting such a licence are met. **(-)** Compulsory licensing may decrease innovation and investment as it may reduce overall revenues from innovation.[6]	SPC	CL
	Cost of compliance	**(+)** Simplification coming with a centralised procedure and unitary SPC should reduce the administrative burdens of applying for SPC, address inconsistent national granting procedures and lower the cost of applying and maintaining the SPC in force. **(+)/(-)** CL will increase cost of compliance for companies when negotiating with Member States. However, EU-wide negotiations will imply costs savings compared to a more fragmented system.[7]	SPC	CL
	International competitiveness	**(+)** The SPC reform aligns European IP practices with international best practices which has the potential to improve the EU's attractiveness as a location for pharmaceutical R&D. **(-)** The impact will depend on when and how EU CL is used. Unpredictable use of EU CL may weaken international competitiveness by undermining investor confidence in returns on innovation and deterring investments in the health technology sector in the EU.	SPC	CL
Market access		Not relevant.		

1) See for example European Commission (2023), Impact Assessment for CL, p. 4, see link. / 2) FTI Consulting for EUCOPE (2024), The Economic Lens: Understanding what makes the EU attractive for life science investments, see link. / 3) See Article 4 in the proposal. / 4) EUCOPE Position Paper on the EU Pharmaceutical Package, July 2023, see link. / 5) Council's position on the EU CL proposal, ST-11613-2024-INIT, published on 26 June 2024, see link. / 6) European Commission (2023), Impact Assessment for CL, p. 44, see link. / 7) European Commission (2023), Impact Assessment for CL, p. 46, see link.

Anticipated legislations

Biotech Act (1/2)

Description	**Problem**	The advances in life sciences, supported by digitalisation and AI, and the potential of solutions based on biology to solve societal issues, make biotechnology and biomanufacturing a very promising technological area. However, the sector is facing challenges with research and technology transfer to the market, regulatory fragmentation and complexity, access to finance, skills, value chain obstacles, intellectual property, public acceptance and economic security.[1]	• The EU's pharmaceutical sector, while contributing greatly to the EU economy as the fifth largest exporting industry and the industry with the highest positive contribution to EU's trade balance in 2022, is outpaced by the US and China in terms of R&D expenditure.[2] • Compared to the US, the EU suffers from a translational gap, driven by a fragmented R&D ecosystem and leading it to underperform when turning knowledge into innovation. • Health biotechnology currently contributes over 80 per cent to the value of the overall biotechnology market and is a key driver of today's innovative medical industry. Biological medicines (including biosimilars) count for around EUR 80 billion revenues, or 40 per cent of overall pharmaceutical sales in the EU.[3] • Gross value added (GVA) from biotechnology reached EUR 38.1 billion in 2022 with healthcare biotechnology as the largest contributor.[4]
	Objective	The Biotech Act will aim to ensure that the EU makes the most of the biotech revolution for the benefit for society, the environment, and the economy. The Act will make it easier to develop and bring products to market across all biotech sectors in the EU.[3,5]	As the EU Biotech Act is still not proposed, the exact provisions are still unknown. However, the following has been put forward in the call for evidence for an impact assessment[5]: • **Speed and streamlining:** Where appropriate, the regulatory environment for biotech will be simplified, including the procedures for risk assessment. This will facilitate and speed up the development and approval of biotech products and bring them to the market faster. • **Access to financing:** Improve existing public activities, incentives and funding schemes under Commission programmes or by EU agencies, together with other EU or national measures will increase access to (risk-tolerant) capital. • **Scale:** Help companies with growing in the EU, including offering support, clusters, investing in infrastructure, etc. • **Skills**: Improve upskilling and reskilling of the workforce in the biotech area. • **Use of data and AI:** Offer access to targeted projects and tailored programmes at EU level to facilitate and push forward the development and adoption of digital solutions and AI in all biotech sectors. • The establishment of the **EU Biotech Hub** in 2024, an operational tool for biotech companies to navigate through the regulatory framework and identify support to scale up.[6]
Overall competitiveness assessment		The EU Biotech Act holds significant promise for enhancing the EU's position as a global leader in biotechnology through bolstering competitiveness. While its potential for the pharmaceutical industry is substantial, its result depends on the level of ambition of the final provisions. The act will only achieve a real leap in competitiveness if it addresses EU's key challenges with complex and fragmented regulatory frameworks, dismantles barriers to the uptake of biotech innovation by national healthcare system and outweighs other legislative initiatives that negatively affect the competitiveness of the sector.	

1) European Commission (2024), Commission takes action to boost biotechnology and biomanufacturing in the EU, see link. / 2) Copenhagen Economics (2024), European trade in pharmaceutical goods, see link. / 3) European Commission (2025), Call for tenders EC-SANTE/2025/OP/0028, see link. / 4) WifOR (2025), Measuring the Economic Footprint of the Biotechnology Industry in the European Union, see link. / 5) European Commission (2025) Call for evidence for an impact assessment, see link. / 6)Your Europe (2025), Biotech and biomanufacturing, see link.

Biotech Act (2/2)

Competitiveness assessment	**Capacity to innovate**	Since the Biotech proposal has not yet been published, the following competitiveness assessment is based on its anticipated objectives and provisions. The proposal aims to simplify and streamline the regulatory framework, which - assuming other factors remain constant - should increase the capacity to innovate. To be truly effective, the Act must align with existing regulations such as the Clinical Trials Regulation (CTR), the Medical Device and In Vitro Diagnostic Regulations (MDR/IVDR), and the GMO Directives. Such alignment is essential to avoid duplication of efforts and to ensure the Act does not merely add another regulatory layer, increasing complexity for companies. **(+)** Increased speed and streamlining of regulatory processes and approval of clinical trials will increase the capacity to innovate, as the uncertainty decreases with speed and streamlining. The simplification of the regulatory framework, if successful, will increase efficiency of regulatory approval thereby cutting time and cost from lab to market. **(+)** The EU Biotech Hub will help companies through the (upcoming simplified) regulatory framework and support to scale up. This will make it easier to conduct business in the EU and increase capacity of innovate and competitiveness. **(+)** The strengthening of R&D ecosystems holds the potential of substantially increasing capacity to innovative through increasing the amount of translational research. **(+)** The focus on access to early, risk-tolerant capital will help especially smaller companies bring products to market. **(+)** Upskilling and reskilling the workforce will provide companies with the right skills, thereby improving productivity and capacity to innovate. **(+)** A focus on supporting start-ups, SMEs, and spin-offs addresses a critical gap in the European innovation system.	
	Cost of compliance	The proposal does not mention anything on cost of compliance or documentation requirements; however, a simplification of rules are expected to decrease the cost of compliance.	
	International competitiveness	The main objective of the Biotech Act is to boost EU competitiveness in the biotechnology and biomanufacturing sector. The Commission's actions to boost biotechnology and biomanufacturing includes multiple measures that will increase international competitiveness, specifically: **(+)** If sufficiently ambitious, the strengthening of the EU R&D ecosystem can improve competitiveness as compared e.g. highly effective US clusters. **(+)** Fostering public and private investment and ensuring help to scale up innovations. All things equal, this will increase international competitiveness, as access to financing and help may get easier. **(+)** Fostering engagement and international cooperation e.g. launching international biotech and biomanufacturing with industrial key partners. This will ensure that the innovations meet international standards and can compete on an international scale. Hence, it can improve international competitiveness.	
Market access		Not relevant.	

Broader policy developments on sustainability and access

Sustainability legislations

Sustainability legislations are essential for the protection of the environment and human health. However, the current regulatory set-up of EU sustainability legislations imposes a cumulative burden, contradictory demands and uncertainty that risks weakening the competitiveness and innovative capacity of the EU pharmaceutical industry. More clarity and coordination of these legislations with other sectoral policies are therefore needed.

Compliance costs increase for companies as sustainability legislations are implemented

With the European Green Deal and broader efforts to deliver a successful green transition, many regulatory changes to enhance sustainability are currently being implemented, see a list of legislations on the next page. While many of these regulations are primarily aimed at chemicals, food, and the environment, some are, for the first time, also integrating medicines within their scope.[1] While this reflects a growing and important political emphasis on sustainability, the **cumulative impact of the concurrent regulatory changes will increase compliance costs**, redirect resources from innovation, and pose challenges for the international competitiveness of the EU pharmaceutical industry.

The regulatory pressure introduces costs and strategic uncertainty

Several proposed or implemented legislations, including GHG reduction targets, the proposed universal restriction on PFAS, and the Urban Wastewater Treatment Directive (UWWD), **require substantial investments and long-term compliance efforts** from pharmaceutical companies. These include detailed chemical mapping, supplier engagement, and the identification of viable alternatives, all of which require time and capital and may affect the availability of certain medicines, e.g. if certain chemical substances get prohibited. Beyond the financial burden, these efforts may also shift resources and investments away from research and development.

New environmental reporting mandates introduce additional compliance requirements that might have an impact on – especially smaller – companies' ability to innovate. In the absence of rewards or incentives for continued green transition investments – as also highlighted in the Draghi report, which notes that decarbonisation efforts should be tied to competitiveness goals - companies may **face increasing costs without clear return on investment.** This is particularly challenging for smaller developers given their relatively more limited financial and operational capacity to absorb additional regulatory expenses without offsetting gains or scalable efficiencies. This will **have negative financial implication** and decrease the competitiveness of pharmaceutical companies operating primarily from the European market.[1]

In parallel, **uncertainty** around the implementation of these legislations adds to the challenge faced by the EU pharmaceutical industry. Companies face unclear implementation timelines, fluctuating cost estimates, and the risk of divergent EU standards. As a result of this uncertainty, companies may reallocate resources from innovation to compliance, and delay or reduce investment in R&D. Ultimately, this also **adds pressure the competitiveness of the EU pharmaceutical industry** which can be critical at a time where the industry is already facing an 'emerging competitive gap' as pointed out in the Draghi report.[2]

Lack of coordination between EU policymakers adds to the regulatory complexity

Beyond the scope of the sustainability legislations, a lack of coordination between health and environmental regulators (e.g. EMA and ECHA) further complicates compliance and adds to the regulatory challenges, see box for an example.

More broadly, inconsistent signals from different regulatory bodies lead to ambiguity over what constitutes sufficient compliance. What satisfies one regulatory body may conflict with another, see box for an example. In other words, companies face unclear benchmarks for compliance, and it becomes very unclear and uncertain when 'enough compliance is enough'.

Going forward and to help support the competitiveness of the EU pharmaceutical industry, **the industry calls for alignment and coordination of policies impacting the pharmaceutical sector**.[1] With this alignment, policymakers should harmonise environmental and health policy goals to avoid contradictory demands and ensure complementarity between regulations to the benefit of the competitiveness of the EU pharmaceutical sector and, ultimately, patients.

> A concrete example on lack of regulatory coordination faced by a pharmaceutical company active in the EU involves a required change to printed packaging materials following the regulation on fluorinated greenhouse gases. The implementation timeline was very short, and the standardised texts were provided late from EMA for implementation on a large number of products. As a result, the company involved had to dispose a large existing packaging stock, update the packaging under pressure, and postpone other key operational activities. This resulted in significant additional costs and resource disruption with risk of shortages in certain countries. This example underscores how misaligned regulatory processes across EU institutions can generate inefficiencies and financial strain based on what may seem like small changes to the product.
>
> *Source: Copenhagen Economics based on interview with a pharmaceutical company.*

1) EFPIA (2025), EFPIA Thematic Analysis on Cumulative Legislative Impacts, see link. / 2) The Draghi Report: In-depth analysis and recommendations (Part B), p. 189, see link.

Sustainability legislations affecting the pharmaceutical industry

Legislative areas				
	Climate & circularity	**General pharma**	**Chemicals**	**Water**
Relevant legislations:	• EU Taxonomy for sustainable activities • Corporate Sustainability Reporting Directive • Corporate Sustainability Due Diligence Directive • Carbon Border Adjustment Mechanism • Industrial Emissions Directive • Packaging and Packaging Waste Regulation • UN Treaty on Plastic Pollution	• General Pharmaceutical Legislation a. Environmental risk assessment (GPL:ERA) b. Good Manufacturing Procedures (GPL:GMP) • Roadmap to phase out animal testing	• One Substance, One Assessment • Essential Use Concept communication • Regulation on the registration, evaluation, authorisation and restriction of chemicals (*REACH review*) • Titanium Dioxide *(Bans & restrictions – TiO_2)* • Per- and polyfluoroalkyl substances *(Bans & restrictions - PFAS)* • Talc *(Bans & restrictions - Talc)* • Octamethylcyclotetrasiloxane (D4), Decamethylcyclopentasiloxane (D5) and Dodecamethylcyclohexasiloxane (D6) *(Bans & restrictions - D4, D5, D6)* • Bisphenol A *(Bans & restrictions - Bisphenol A)* • Polyvinyl chloride *(Bans & restrictions - PVC)* • Nitrosamines *(Bans & restrictions - Nitrosamines)* • F-gas Regulation *(Bans & restrictions - F-gas)* • Synthetic polymer microparticles (formally microplastics) *(Bans & restrictions - SPM)* • Classification, labelling, and packaging of chemicals *(CLP)*	• Urban Wastewater Treatment Directive Water Framework Directive

Source: List adopted from legislations covered in EFPIA (2025), EFPIA Thematic Analysis on Cumulative Legislative Impacts, see link.

AUTHORS

Julia Wahl, Partner
Malwina Mejer, Senior Economist
Lærke Kilsdal, Lead Economist

Copenhagen Economics A/S

Langebrogade 3C
DK-1411 Copenhagen
Denmark

Lilla Nygatan 14
SE-111 28 Stockholm
Sweden

Lönnrotinkatu 5
FIN-00100 Helsinki
Finland

Maison de la Radio
Place Eugène Flagey 18
BE-1050 Brussels
Belgium