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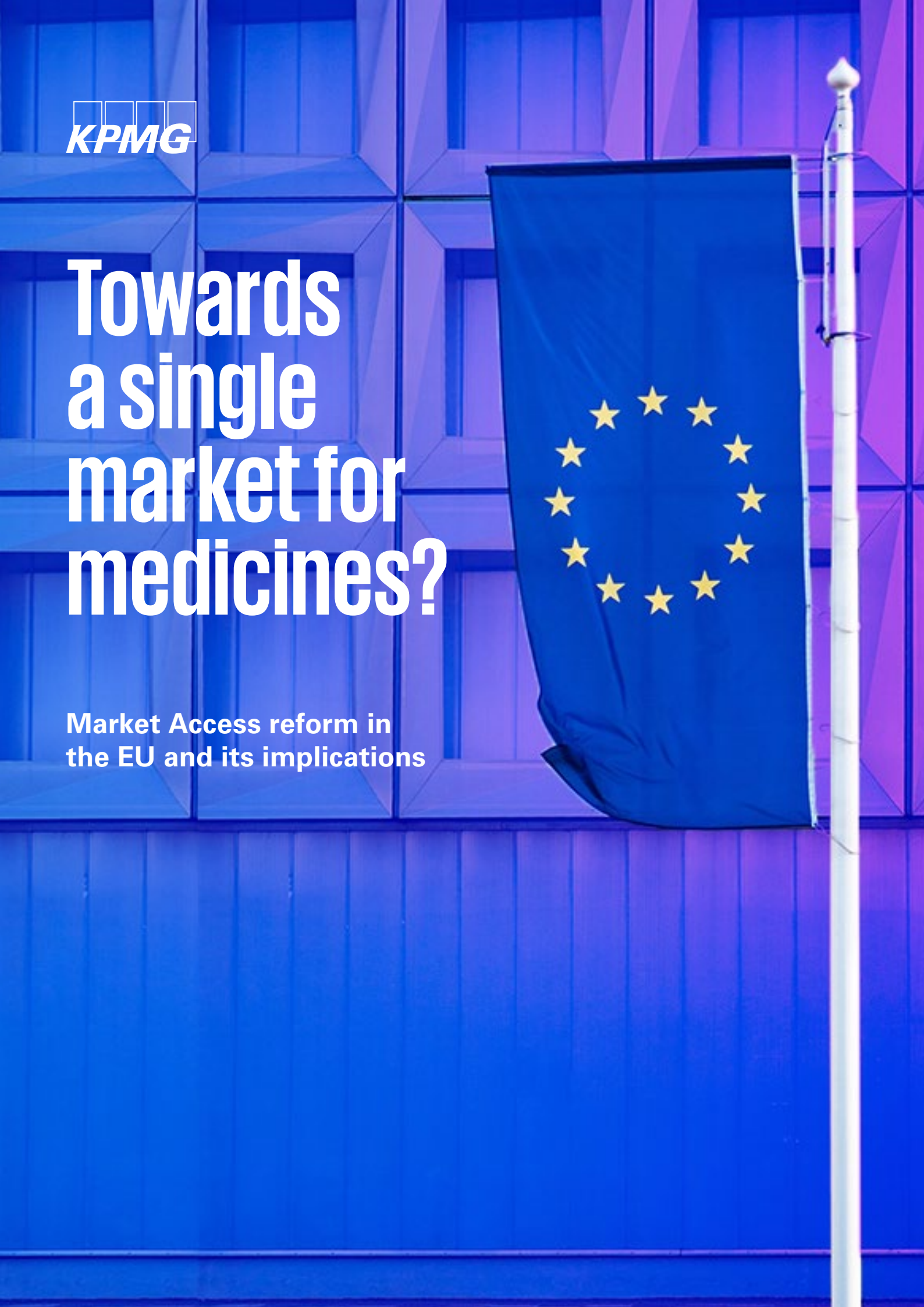
Towards a single market for medicines?

Market Access reform in the EU and its implications

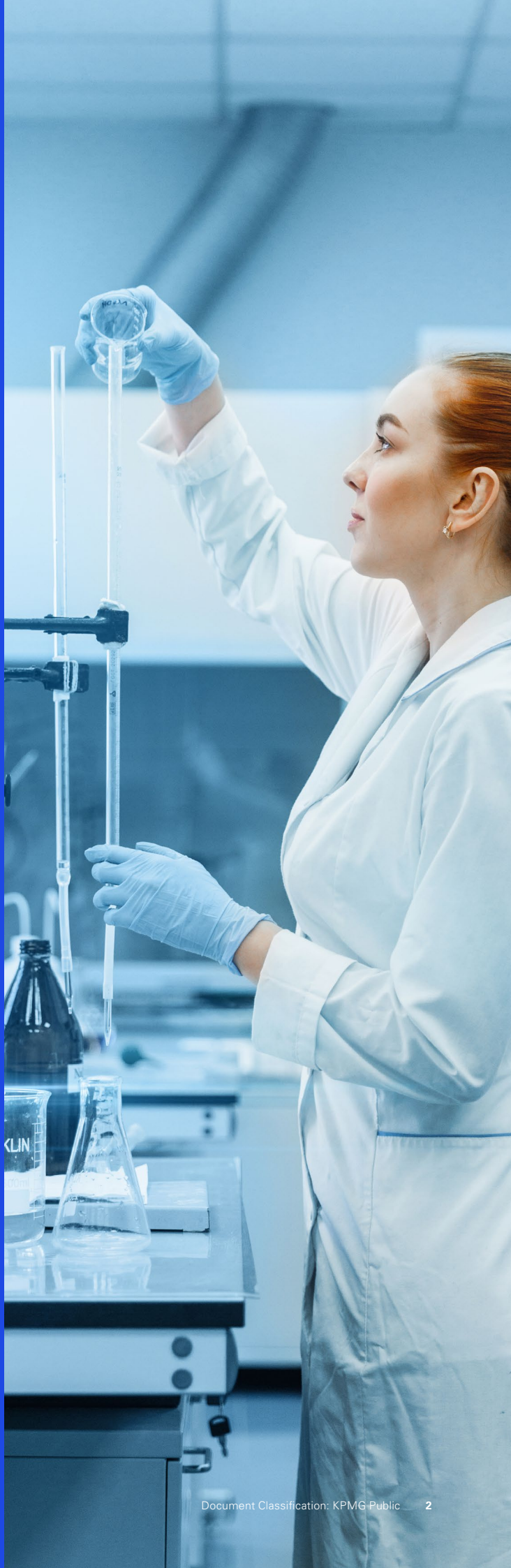


"We cannot have first and second-class citizens when it comes to accessing medicines in the EU[1]"

Equality of access is what EU Health & Food Safety Commissioner Stella Kyriakides stressed was the driving factor behind reform to EU Pharmaceutical Legislation, announced in April 2023[1].

Whilst addressing unequal access to medicines across the single market is cited as the primary driver, change represents the latest iteration of the continual drive for healthcare integration. New EU regulation on Health Technology Assessment (HTA) will come into effect from 2025, introducing Joint Clinical Assessments across the EU for new medicines, beginning initially with Cancer medicines[2]. Similarly, the EU Digital COVID certificate and role of the European Commission in vaccine procurement[3] represents an unprecedented extension of the EU's role in healthcare.

Though the proposed changes in the EU are less extensive compared with the Inflation Reduction Act in the US, with no direct impact on drug pricing, it's imperative that Pharma and Biotech companies begin to consider their portfolio strategies and how they perform their go-to-market activities, amidst the wider context of a more integrated EU healthcare market.



What changes are the EU proposing?

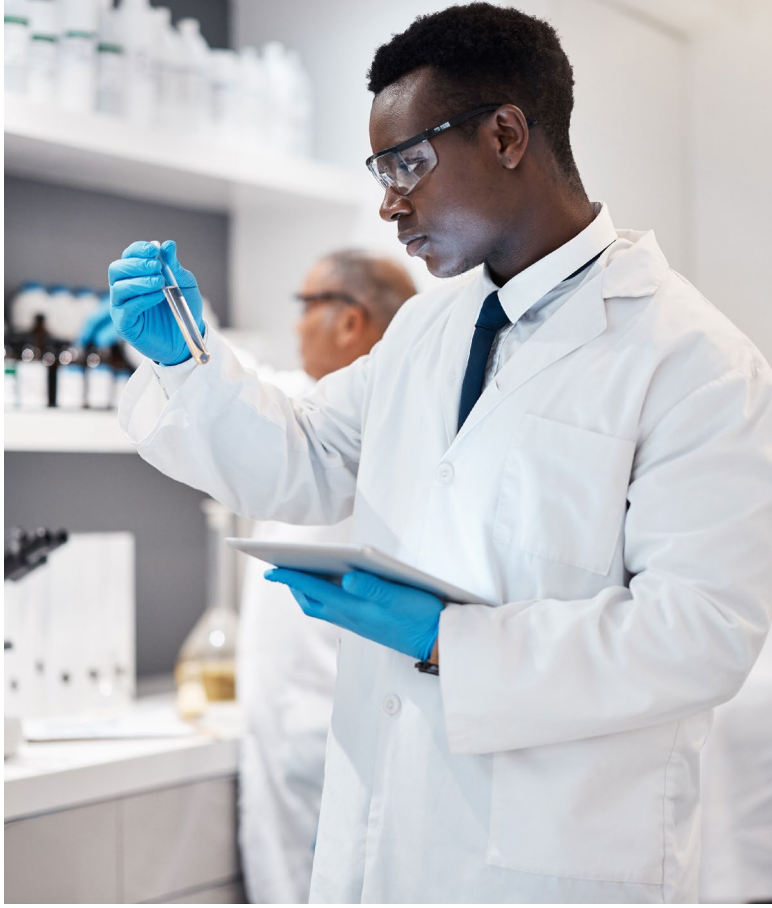
A modular scheme of incentives governing new medicines

In addition to 8 years of data protection, additional incentives could extend protection up to a maximum of 12 years[4], including:

Measure	Additional protection offered
Launching across **all member states**	2 years
Developing the medicine in **new indications**	1 year
Addressing an **unmet medical need**, for life threatening or debilitating diseases that are not treated effectively	6 months
Conducting head-to-head **comparative clinical trials** against existing products	6 months

A changed regime of incentives for orphan medicines

Rules for orphan medicines will differ than those for non-orphan medicines, to offer greater incentives for investment in rare diseases. Currently orphan indications benefit from 10 years of market exclusivity associated with the indication rather than the medicine, protecting them from like-for-like competition[5] for that particular indication. Going forward, it is proposed that the minimum marketing exclusivity for orphan medicines would be 9 years, with similar incentives offering the opportunity to extend it to 13 years if conditions including addressing significant unmet needs are met. That said, the changes represent a rollback in some respects, with a shift from conferring exclusivity on an indication basis, as occurs now[6] towards providing additional incentives for further indications, with a report commissioned by the European Federation of Pharmaceutical Industries and Associations (EFPIA) finding that 'the Commission chose to chip away at incentives for innovation'[7] .



Incentives to address anti-microbial resistance (AMR)

Incentives to tackle anti-microbial resistance form part of the proposed legislation through transferable data vouchers. The vouchers, which can be sold on by pharma companies and used for any new medicine, will offer an additional year of data protection for manufacturers, and form part of a broader package, including encouraging member states to put into place National Action Plans for AMR by June 2024.[8]

EU-level management of potential supply chain issues

Greater focus is placed on manufacturers and members states to manage the threat of shortages. Companies with products on the market are obliged to put into place shortage prevention plans, whilst member states must continually monitor potential shortages.[9] The proposals cement the role of the the Executive Steering Group on Shortages and Safety of Medicinal Products (the 'Medicine Shortages Steering Group – MSSG') which was established in response to the pandemic,[10] to manage potential supply chain disruptions. Critical shortages will be tracked at an EU-wide level, and the MSSG can recommend actions to safeguard the quality, safety and efficacy of medicinal products as security of the supplies, to manufacturers, member states and the EU Commission.

Reforms to the EU's Regulatory Framework and Processes

Emphasis has been put on streamlining EMA structures and functions to improve the effectiveness of regulatory frameworks. Changes including the simplification of the EMA's scientific committees and working parties will enable the reduction of the EMA's scientific evaluation period from 210 to 180 days.[11]

Why is reform happening now?

> **The European Health Union is not a concept, a slogan, a verbal objective. It is action and it is happening [12]**
>
> Vice-President Schinas, 26 April 2023

Addressing inequalities across the EU

Rather than a lack of access to innovative medicine, inequality of access is cited as a driving factor for change. The average time it takes for a new medicine to become available in a European market is 517 days[13], but within this there are vast disparities across countries, from 129 days in Germany to countries including Poland, Romania and Malta where the average is longer than 2 years.[14] Moreover, the availability of medicines across EU members states (when they are ready to prescribe to patients) is inconsistent, with the average rate of availability of medicines across EU countries 45%, and lower in Orphan medicines at only 39%[15]. This inequality has prompted the inclusion of the EU's tapered regime of incentives, and particularly the requirement to launch across all EU markets to unlock the full potential exclusivity of products. The proposal puts a ticking clock on negotiations with nation states, via the requirement that manufacturers must launch 'within two years from the marketing authorisation (or within three years in the case of SMEs, not-for-profit entities or companies with limited experience in the EU system)'.[16]

However, industry players dispute the wisdom of the EU's sole focus on manufacturers. EFPIA outline that delays and inequalities in access stem from a range of factors, many of which are beyond manufacturers control including national level evidence requirements and resources constraints.[17] In this respect, the proposed reform places the burden for national level launches on manufacturers alone, and threatens to undercut the negotiating position of manufacturers, creating a ticking clock on negotiations with payers that can be used against them. Equally, it will prove difficult to enact in practice. Simultaneous launches across European markets can prove a challenge now, given the effort involved in managing the multiple national reimbursement processes that need to be adhered to. This is without considering other complexities, such as how the use of external reference pricing in some markets means an agreement concluded in a less lucrative EU country could shape the price in another.

Tackling antimicrobial resistance and improving supply chain resilience

Antimicrobial resistance and the insecurity of supply chains are at the forefront of the thinking in the broader raft of changes being introduced. The measures taken in these demonstrate the EU's willingness to potentially increases the costs for European healthcare systems to stimulate innovation. Estimates on the cost of a year-long transferable exclusivity vouchers on European healthcare systems range from less than €1 billion to more than €3 billion[18]. That said, these transferable vouchers will provide the added incentive to encourage R&D in the space. Hospitals will typically prescribe cheaper, generic antibiotics[19] meaning that garnering sufficient revenue these products can be challenge, with estimated development costs of between $568m and $700m[20] . Though countries including the UK and France are increasingly offering 'pull' incentives like subscription payments and minimum prices, few large pharma companies have antibiotics in development[21].

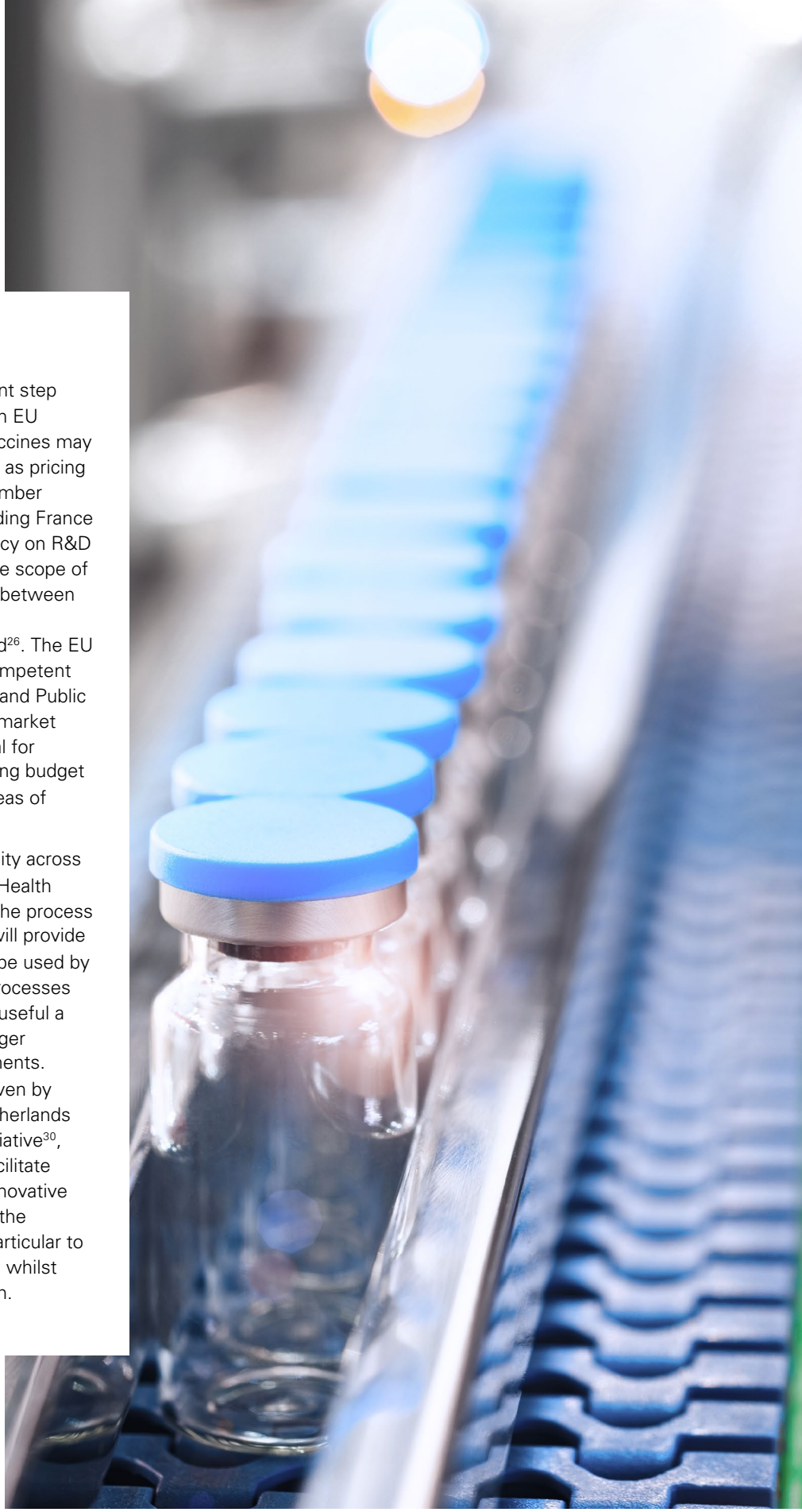
Estimates from the Office of Health Economics found that vouchers could be worth up to €800 million in the open market,[22] and the sheer value of these could help to address the gap between the revenue of anti-microbials and costs in developing them compared with more incremental measures.

Whilst outright measures to secure European supply chains are not a feature of the draft legislation, it creates the framework to begin to do so, and further the goal of 'open strategic autonomy'[23] cited as an aim of the 2020 Pharmaceutical Strategy for Europe. There is scope for the EU to impose contingency stock requirements, or other obligations on manufacturers to secure supplies. Quite how these powers will be used is not clear, with re-shoring of API production[24] and availability of generic medicines likely to be amongst the future areas of focus.

Harmonising the approaches of member states

More broadly, reform represents a significant step towards an integrated health union between EU states. Common procurement of COVID vaccines may become a template for future EU measures as pricing transparency is increasingly in focus for member states, with measures from countries including France and Italy aimed at seeking more transparency on R&D costs to inform pricing.[25] Whilst currently the scope of EU action centres on enabling co-operation between member states, there are signs that future collaboration could become more formalised[26]. The EU established a regular forum for 'National Competent Authorities on Pricing and Reimbursement and Public Healthcare Payers'[27] to discuss pricing and market access issues, with areas including potential for collaboration during negotiations and ensuring budget sustainability through competition future areas of discussion[28].

Joint HTAs are already set to become a reality across the EU, through the European Network for Health Technology Assessment consortium, with the process launching in 2025 for cancer medicines. It will provide an EU wide information dossier, that could be used by member states to augment national level processes for pricing and market access, though how useful a European HTA will be is disputed[29], with larger markets unlikely to align their HTA requirements. Impetus for reform in the area has been driven by members states. In 2015, Belgium, the Netherlands and Luxembourg formed the 'Beneluxa' initiative[30], later incorporating Austria and Ireland, to facilitate greater collaboration on the evaluation of innovative medicines. Such collaborations underscore the appetite of smaller European countries in particular to ensure fast access to innovative medicines, whilst achieving value for money in procuring them.



Key Takeaways

EU Reform will shift the dial on investment and commercial planning decisions

As with the impact of the Inflation Reduction Act in the US, EU Pharma reforms alter the R&D incentives for companies seeking to enter the European market. However, unlike the Inflation Reduction Act, which will shape investment decisions in terms of small molecules compared to biologics[31], companies will need to develop regulatory strategies to demonstrate eligibility for incentives such as additional market exclusivity periods across Europe.

EU states are collaborating more closely and widely on health policy

Greater collaboration between member states has been developing over the last decade, and brings risks and opportunities to pharma companies. Sharing of information, and common negotiation could be used to squeeze prices, though also offers scope to reduce the administrative burden of bringing products to market.

It will become increasingly important for life science companies to better understand which expedited drug approval pathways may be open to them and the impact on approval times for innovative medicines - working closely with payers to bridge hurdles to bringing new therapies to market.

KPMG's Healthcare and Life Sciences experts in the UK and across Europe can support you with Pricing and Market Access, Regulatory Affairs and Commercial Operating Model development, to help you plan for the impact of EU Pharma Reform.

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Key Contacts

Adrian Griffiths
Partner
Head of Life Sciences,
UK
Adrian.griffiths@kpmg.co.uk

Guillaume Favier PhD
Partner
Healthcare and
Life Sciences Strategy, UK
guillaume.favier@kpmg.co.uk

Sophia Economides
Associate Director
Pricing and
Market Access Lead, UK
sophia.economides@kpmg.co.uk

James Healy
Senior Associate
Healthcare and
Life Sciences Strategy, UK
james.healy3@kpmg.co.uk

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