SQUIRE PATTON BOGGS

EU Pharmaceutical Strategy

1 December 2020

The European Commission President Ursula von der Leyen has put an emphasis on health policy since the beginning of her term, by promoting the development of a number of initiatives that will be published in the months and years to come.

Inevitably, the COVID-19 pandemic has generated a growing demand for better coordination across EU Member States in connection to the management of health systems and health emergency response, an area in which Member States opted to maintain full competence.

A new Pharmaceutical Strategy for Europe, published on 25 November has been one of those initiatives, which aim to establish a future-proof and crisis-resilient pharmaceutical system in the EU. In this client alert, we are looking into the strategy and the future initiatives stemming from the strategy, as well as future health policies that can be expected.

Pharmaceutical Strategy for Europe

The recently published Pharmaceutical Strategy for Europe puts forward a patient-centric EU approach to pharmaceutical policy that envisages to draw from the potential of the digital transformation of health care, to ensure the quality and safety of medicines and to build a stronger European Health Union. The Strategy is developed to also contribute to existing EU policy initiatives, such as Europe's Beating Cancer Plan (expected to be published in December 2020), the European Green Deal, the Chemicals Strategy for Sustainability, the new EU Industrial Strategy and the European Digital Strategy.

The Pharmaceutical Strategy is built on four pillars and proposes a number of initiatives:

I. Access and affordability of medicines

Addressing unmet needs is a key component of the Strategy. Access to safe and effective medicines, promoting innovation in a patient-centric manner, looking into actions to tackle anti-microbial resistance, as well as promoting further investment towards the research and development (R&D) of medicines for unmet needs and therapies for emerging health threats, are highlighted as priorities in this context.

To ensure research priorities are aligned to the needs of patients and health systems, the European Commission proposes through various initiatives, such as further incentives for scientific collaboration between stakeholders (e.g. industry, regulators, academia, healthcare professionals, patients' organizations and payers), reinforced cross-country collaboration in public procurement, pricing and reimbursement, as well as health technology assessment.

The fact that access and price of medicines varies significantly across Member States due to the different pricing and reimbursement policies, organization of health systems, national administrative procedures and market size, as well as lack of transparency and consensus on costing principles and R&D costs, are restricting a coordinated EU approach on affordability and accessibility of medicines. Therefore, the European Commission deems it necessary to review the system of incentives, improve the competition of generic and biosimilar medicines, review the EU competition rules in the pharmaceutical sector as crucial factors to improve the access and affordability of medicines. Importantly, the European Commission notes that the lack of competition in the pharmaceutical market can hinder price savings when innovative products lose their market exclusivity. The Commission will also continue to carefully review mergers between pharmaceutical companies to avoid distortion of competition.

II. Supporting a competitive and innovative European pharmaceutical industry

To support the competitiveness and resilience of the European pharmaceutical industry, the European Commission envisages establishing a stable and flexible regulatory environment that would provide legal certainty for investments and accommodate new technologies. Contributing to this objective would be a revised intellectual property rights regime outlined in a recently published Intellectual Property Rights Action Plan, leveraging the potential of health data, and accessing a skilled workforce and funding.

Enabling innovation and digital transformation can contribute to improve patients' health and support a more efficient and cost-effective manner to discover and use medicines. As such, challenges linked to developing advanced therapy medicinal products and adapting to the increasing number of gene and cell therapies under development should be addressed through this Strategy.

In particular, the European Commission underlines the importance of maintaining regulatory efficiency throughout the entire lifecycle of medicines. To achieve that the role of the network of national medicines agencies should be reinforced, alongside regulatory approval times, simplifying and streamlining authorisation and monitoring procedures, and enhancing the use of digital solutions.

However, the classification and challenges linked to other regulatory procedures and the regulatory requirements for human medicines containing genetically modified organism (GMOs) should be improved.

III. Enhancing resilience in the EU by introducing a diversified supply chain, sustainable pharmaceuticals and crisis preparedness

The COVID-19 pandemic has demonstrated more than ever how a shortage of medicines can compromise patients' health and increase the burden on healthcare systems and professionals. To overcome this difficulty, the European Commission stresses that marketing strategies, parallel trade, scarce active pharmaceutical ingredients and raw materials, weak public service obligations, supply quotas or issues linked to pricing and reimbursement would be key elements to assess in future policies.

Thus, securing the supply of medicines and ensuring the quality, safety, and sustainability of medicines are principal elements of the Strategy. To that effect, strengthening oversight and transparency of the global manufacturing chain will be important.

With regard to the EU's health crisis response mechanisms, the Strategy lays out future initiatives that would feed into the EU's preparedness and resilience to cross-border health threats, building on the recent proposals in respect of a European Health Union.

IV. Ensuring EU influence and competitiveness on a global level

The Strategy envisages enhancing the EU's influence and competitiveness on the international scene by promoting common international standards, a level playing field, and a regulatory environment conducive to innovation and competitiveness. It commits to supporting the work of the World Health Organisation to strengthen regulatory capacity globally. The European Commission would promote bilateral cooperation for regulatory convergence to address access to safe, effective high quality and affordable medicinal products globally.

What to Expect?

In 2021

- Regulation on a European Health Data Space (legislative);
- Revision of the European Medicines Agency (EMA) fee Regulation (EU) 658/2014 (legislative);
- Regulation to create an EU Health Emergency Response Authority (HERA) (legislative);
- Fully implement the regulatory framework for clinical trials;
- Propose non-legislative measures and optimize the use of existing regulatory tools to combat antimicrobial resistance and incentives for R&D of antimicrobials;
- Promote investment and coordinate the research, development, manufacturing, deployment, and use of novel antibiotics as part of the future HERA;
- Facilitate collaboration on unmet needs and evidence generations between health technology assessment (HTA) bodies and work towards the adoption of the proposal for a Regulation on HTA;
- Initiate a pilot together with the EMA and Member States, with the engagement of future marketing authorisation holders, to understand the main reasons of deferred market launches;
- Encourage buyers from the health sector to cooperate in view of implementing innovative procurement approaches for the purchases of medicine or medical devices, in the framework of the Big Buyers initiative;
- Launch a pilot project with engagement of industry and academia to test a framework for the repurposing of off-patent medicines and inform possible regulatory action;
- Launch a vaccine platform to monitor the effectiveness and safety of vaccines, supported by an EU-wide clinical trials network;
- Upgrade the EU's Register of centrally authorised medicines;
- Launch a structured dialogue between the players in the pharmaceuticals manufacturing value chain and public authorities to identify vulnerabilities in the global supply chain in order to formulate policy options and propose actions to strengthen the continuity and security of supply in the EU; and
- Consider actions to ensure that the industry increases transparency in supply chains through a voluntary process.

In 2022

- Revision of the Regulation (EC) 1901/2006 on medicinal products for paediatric use and Regulation (EC) 141/2000 on orphan medicinal products (legislative). A public consultation to gather stakeholder input on the two revisions is currently ongoing, until 6 January 2021, with a longer survey-based consultation foreseen in the first quarter of 2021;
- Review of Directive 2001/83/EC on the code relating to medicinal products for human use and Regulation (EC) 726/2004 laying down the procedures for the authorisation and supervision of medicinal products for human use (legislative). The following elements are expected to be taken into account in this revision:
  - Address market competition considerations, including interchangeability and the 'Bolar exemption', aspects that impede the competitive functioning of the markets;
  - Simplify and streamline the approval procedure, address the challenges related to the interplay of medicines and medical devices, and strengthen pro-competitive elements;
  - Revise the manufacturing and supply provisions to improve the transparency and reinforce oversight of the supply chain and clarify responsibilities to ensure overall environmental sustainability, safeguard the quality of medicines and ensure preparedness for new manufacturing technologies as well as to enhance the security of supply and address shortages;
  - Introduce provisions that would facilitate cutting-edge products, scientific developments and technological transformation, and revise the variation framework for medicines, to make the lifecycle management of medicines more efficient and adapted to digitalization;
  - Consider adapting the regulatory requirements applicable to medicines containing GMOs;
  - Restrict, optimise and revise the system of incentives and obligations for antimicrobials;
  - Strengthen the environmental risk assessment and conditions of use of medicines;
- Revise Regulation (EC) 234/2008 to extend powers of regulators to adjust variations to the terms of marketing authorisations for medicinal products for human use (legislative) on the basis of scientific evidence;
- Incorporate the EMA's priority medicines scheme (PRIME) in the regulatory framework to provide enhanced support to accelerate product development and authorisation in areas of unmet needs;
- Initiate regulatory pilots in a 'sandbox' environment provided by the EMA and the Commission to test the adaptability of the pharmaceutical framework for new cutting-edge product developments;
- Provide for a single assessment process across Member States for active substances used for different generic medicines (active substance master files) to facilitate their authorisation and life-cycle management;
- Optimise the supplementary protection certificates system, to make it more transparent and efficient as foreseen in the Intellectual Property Action Plan; and
- Strengthen support and training of academia and not-for-profit organisations in regulatory science for better translation of research into product development.

Long-term Measures

Next to future legislative changes, the European Commission also envisages long-term measures that can contribute to the four pillars of the Strategy, such as:

- Encouraging Member States and provide support to engage in close cooperation through funding provided by EU4Health to develop guidelines, measures and tools that could be used both at EU level and in national policy-making to address structural shortages;
- Engaging with Members States to implement non-legislative measures to improve transparency, such as guidelines on principles and costing methods for establishing the R&D costs of medicines;
- Establish interoperable data access infrastructure for the European Health Data Space;
- Establish secure federated access to 10 million genomes across borders for research, innovation and clinical applications, including on personalised medicines; and
- Simplify and streamline the system of penalties to address non-compliance in a proportionate and efficient way.

It is worth noting that the European Health Union published on 11 November 2020, has already put forward three legislative proposals which are linked to the Pharmaceutical Strategy:

- **Proposal for Regulation** on serious cross-border threats to health, which proposes among others to develop an EU health crisis and pandemic preparedness plan as well as recommendations for the adoption of plans at national level which will undergo through an EU audit to assess their effectiveness and preparedness;
- **Proposal for Regulation** to reinforce the role of the EMA, to regularly monitor events that could lead to a public health emergency or pose a serious risk to public health. It also proposes to establish an EMA Executive Steering Group on Shortages and Safety of Medicinal Products, which would be examining the need for action and provide assistance to address such events. The proposal also provides for obligations on Member States, medical device manufacturers, authorised representatives, and notified bodies to facilitate the monitoring of shortages of medical devices; and
- **Proposal** for a Regulation to reinforce the mandate of the European Centre for Disease Prevention and Control (ECDC) to, among others, monitor and assess health systems' capacities and to develop prevention and response plans against future pandemics, coupled with an integrated rapid epidemic and outbreak response at a national level.

Conclusions

The Strategy outlines a broad range of measures that would be determining the policy developments in the pharmaceutical sector in the coming years. Through the 4 pillars outlined in the Strategy, the European Commission aims to ensure the resilience of medicine supply chains and build up the EU's open strategy autonomy, a key theme for the von der Leyen Commission.

Member State competence on healthcare matters suggests that some of the proposed policy measures would be of a voluntary nature. However, European Commission President, Ursula von der Leyen, intends to bring forward the question of health competences during the Conference on the Future of Europe, a milestone to shape the medium- to long-term EU policies. Considering the strong preference of Member States in proclaiming the principle of subsidiary in health matters, it is unclear at this point whether any tangible political changes can be foreseen in this context.

The Pharmaceutical Strategy is only part of broader efforts of the European Commission to reinforce the EU's response to healthcare policies. The recently published Communication on building a European Health Union, is another step to promote existing structures and mechanisms for better EU-level health protection, reinforced cross-border cooperation and a greater role in global coordination and cooperation on cross-border health threats.

Inevitably, the comprehensive list of initiatives, would initiate future lengthy discussions that could lead to definitive changes of the pharmaceutical legislative regime. The regulatory and Intellectual Property revisions may transform the balance between incentives and rewards for pharmaceutical companies, particularly concerning Supplementary Protection Certificates (SPCs) and patent term extension, both fundamentally important for the pharmaceutical industry.

The revision of the primary pharmaceutical legislation, coupled with the Pharmaceutical Strategy's increased emphasis on access and affordability of medicines, supply chain resilience, market authorisations and competition principles, could have far-reaching effects on the pharmaceutical industry and the healthcare industry at large.

About Us

As a full-service global law firm, we provide insight at the point where law, business and government meet, giving our clients a voice, supporting their ambitions and achieving successful outcomes. Our multidisciplinary team of more than 1,500 lawyers and public policy experts in 45 offices across 20 countries provides unrivalled access to expertise and invaluable connections on the ground. It is a seamless service that operates on any scale – locally or globally. It encompasses virtually every matter, jurisdiction and market. And we place our clients at the centre.

We combine sound legal counsel with a deep knowledge of our clients' businesses to resolve their legal, public policy and political challenges. We care about the quality of our services, the success of our clients and the relationships that are forged through those successes. Our client base spans every type of business, both private and public, worldwide. We advise a diverse mix of clients, from Fortune 100 and FTSE 100 corporations to emerging companies, and from individuals to local and national governments. Leveraging local connections, while exerting global influence, we are commercial, connected and committed.

Our Public Policy Practice Group works with clients to make sure they are heard, at the right time, by the right people, with the right message in Washington DC, Brussels, London, Canberra and other major capitals around the world.

Visit our European Public Policy and International Policy webpages for more information on our team and capabilities.

Contacts

Diarmuid Ryan
Partner, London
T +44 207 655 1310
E diarmuid.ryan@squirepb.com

Francesco Liberatore
Partner, London
T +44 207 655 1505
E francesco.liberatore@squirepb.com

William Downs
Partner, Leeds
T +44 113 284 7464
E william.downs@squirepb.com

Matthew Kirk
International Affairs Advisor, London
T +44 20 7655 1389
E matthew.kirk@squirepb.com

Adrian Spooner
Consultant, London
T +44 20 7655 1067
E adrian.spooner@squirepb.com

Wolfgang Maschek
Partner, Chair of European Public Policy Practice, Brussels
T +32 2 627 1104
E wolfgang.maschek@squirepb.com

Ian Tully
Partner, Milan
T +39 02 1241 27702
E ian.tully@squirepb.com

Christina Economides
Public Policy Advisor, Brussels
T +32 2 627 1105
E christina.economides@squirepb.com